Introduction

Men in the United States get prostate cancer more than any other type of cancer except skin cancer. It is found mainly in older men. In the United States, about one out of five men will be diagnosed with prostate cancer. Most men diagnosed with prostate cancer do not die of it.

Complementary and alternative medicine (CAM) is a form of treatment used in addition to (complementary) or instead of (alternative) standard treatments. CAM treatments generally are not considered standard medical approaches. Standard treatments go through a long and careful research process to prove they are safe and effective, but less is known about most types of CAM.

CAM use among prostate cancer patients is reported to be common. CAM treatments used by prostate cancer patients include certain foods, dietary supplements, herbs, vitamins, and minerals.

This PDQ summary gives general information about using foods and dietary supplements to lower the risk of developing prostate cancer or for treating prostate cancer, its symptoms, or side effects of disease treatment. In addition, this summary has sections for several specific foods or dietary supplements:

- Calcium
- Green Tea
- Lycopene
- Modified Citrus Pectin
- Pomegranate
- Selenium
- Soy
- Vitamin D
- Vitamin E
- Combination Therapies
- Other Prostate Health Supplements
More topics will be added over time. These sections include the following information for each food or dietary supplement:

- How it is given or consumed.
- Reviews of laboratory and animal studies.
- Results of population studies and clinical trials.
- Side effects or risks.
- Food and Drug Administration (FDA) information.

**Overview of CAM Use in Prostate Cancer**

Studies of CAM use to treat prostate cancer have shown the following:

- Men who have prostate cancer are more likely to take dietary supplements than men who do not have prostate cancer.
- Prostate cancer patients with the healthiest eating habits (for example, eating lots of fish rich in omega-3 fatty acids and vegetables) are the most likely to take dietary supplements.
- Reasons given by prostate cancer patients for using CAM treatments include boosting the immune system, improving quality of life, and lowering the risk of the cancer coming back.

Studies of CAM use to lower the risk of developing prostate cancer or to prevent it from coming back have shown the following:

- A study of men with a family history of prostate cancer found that over half used vitamins or other dietary supplements, including those sold for prostate health or cancer prevention, such as some of those listed in this summary.
- A study of men at a prostate cancer screening clinic found that well over half took multivitamins and a smaller number took herbal supplements.
- A study of prostate cancer survivors found that up to one-third took vitamins or minerals.
- Although many prostate cancer patients use CAM therapies, only about half of them tell their doctors about their use of CAM.

Studies of why prostate cancer patients do or don't decide to use CAM show that their choice is based on many factors, including their medical history, their beliefs about the safety and side effects of CAM compared to standard treatments, and their need to feel in control of their treatment.

**Questions and Answers About Calcium**

1. **What is calcium?**
   
   Calcium is a mineral that is needed for basic blood vessel, muscle, and nerve functions, cell-to-cell signaling, and hormone release. It is the most common mineral in the body. The body stores calcium mainly in bone tissue. Calcium naturally occurs in some foods and is added to other foods. It is also available as a dietary supplement.

2. **How is calcium administered or consumed?**

   The main sources of calcium in the American diet are foods and dietary supplements. About one-third of dietary calcium comes from milk and milk products like cheese and yogurt. Vegetable sources include Chinese cabbage, kale, and broccoli. Spinach contains calcium but it is not in a form that is well absorbed by the body. Foods with calcium added include many fruit juices and drinks, tofu, and cereals.

   In the United States, almost half the population takes dietary supplements containing calcium. However, most research about calcium and prostate cancer risk has studied only calcium consumed in the diet and not calcium
3. Have any preclinical (laboratory or animal) studies been conducted using calcium?

Laboratory and animal research has been done to study the effects of calcium in prostate cancer.

Studies of calcium in the laboratory have shown the following:
- In a 2011 study, prostate cancer cells were treated with cow milk, almond milk, soy milk, casein, or lactose. Growth of prostate cancer cells (LNCaP) was stimulated when they were treated with cow milk. Treatment with soy milk did not affect the growth of prostate cancer cells, and treatment with almond milk treatment slowed the growth of prostate cancer cells.

Studies of calcium in animal models of prostate cancer have shown the following:
- Strains of mice which developed prostate cancer that acts like human cancer were fed low-calcium diets or high-calcium diets. Prostate cancer growth was found to be similar in mice fed either low- or high-calcium diets.
- Dietary vitamin D and calcium were studied in mice injected with prostate cancer cells and fed specific diets (including high-calcium plus vitamin D or normal calcium and no vitamin D). The mice that received the normal calcium and no vitamin D diet had more prostate cancer growth than mice fed the other diets.

4. Have any clinical trials (research studies with people) of calcium been conducted?

Studies of people in many parts of the world have been done to find out if there is a link between dairy products, calcium, and prostate cancer risk.

Population studies

Population studies look for risk factors and ways to control disease in large groups of people.

Population studies of dairy products, dietary calcium, and prostate cancer risk have shown mixed results. These studies may be hard to interpret because other major nutrients in dairy products, such as fats, and factors such as age and body mass index have not been taken into account.

Overall, however, studies suggest that high total calcium intake may be linked with increased risk of advanced and metastatic prostate cancer compared with lower amounts of calcium. More studies are needed about the effects of calcium and/or dairy products on prostate cancer risk and how these effects develop in the body.

Clinical trial of preventing prostate cancer

In a randomized clinical trial reported in 2005, men were given calcium (1200 mg/day) or a placebo for 4 years and were followed up for 12 years. During the first 6 years of the study, there were markedly fewer cases of prostate cancer in the calcium group compared to the placebo group. After 10 years, however, there was no meaningful difference in the number of prostate cancers in the calcium group compared to the placebo group.

Reviews of many studies combined

Reviews of many studies combined showed mixed findings about whether consuming calcium and dairy products affects the risk of prostate cancer:
- A 2005 review of many studies found a possible link between an increased risk of prostate cancer and a diet high in dairy products and calcium. See the PDQ summary on Prostate Cancer Prevention for more information.
- A 2008 review of 45 observational studies found no link between consuming dairy products and the risk of prostate cancer.
- A review of cohort studies published between 1996 and 2006 found that consuming milk and dairy products did increase the risk of prostate cancer.
- A 2013 review for the U.S. Preventive Services Task Force found that taking Vitamin D and/or calcium...
supplements showed no overall effect on rates of cancer or deaths from cancer, including prostate cancer.

- A 2015 review of 32 cohort studies found that consuming high amounts of milk, low-fat milk, cheese, total dietary calcium, and dairy calcium may increase the risk of prostate cancer. Calcium supplements and non-dairy calcium were not linked with an increased risk of prostate cancer. Calcium supplements were linked with an increased risk of dying from prostate cancer, suggesting that more studies are needed.

5. **Is calcium approved by the U.S. Food and Drug Administration (FDA) for use as a cancer treatment in the United States?**

The U.S. Food and Drug Administration has not approved the use of calcium as a treatment for cancer or any other medical condition.

Calcium is available in the United States in food products and dietary supplements. Dietary supplements are products meant to be added to the diet. They are not drugs and are not meant to treat, prevent, or cure diseases. The manufacturer is responsible for ensuring that the product is safe and that the label claims are truthful and not misleading. The FDA does not approve dietary supplements as safe or effective before they are sold.

**Current Clinical Trials**

Check the list of NCI-supported cancer clinical trials for CAM clinical trials on calcium carbonate for prostate cancer and calcium citrate for prostate cancer that are actively enrolling patients.

General information about clinical trials is also available from the NCI website.

**Questions and Answers About Green Tea**

1. **What is green tea?**

Tea has been consumed in Asia since ancient times. Sailors first brought tea to England in the 17th century. Other than water, tea is the most widely consumed beverage in the world. Tea comes from the *Camellia sinensis* plant. The way the leaves of this plant are processed determines the type of tea produced.

Many of the possible health benefits studied in green tea are thought to be from compounds called polyphenols. Polyphenols are a large group of plant chemicals that include catechins (antioxidants that help protect cells from damage caused by free radicals).

Catechins make up most of the polyphenols in green tea. Green tea catechins (GTCs) include:

- (−)-epigallocatechin-3-gallate (EGCG).
- (−)-epicatechin (EC).
- (−)-epicatechin-3-gallate (EGC).
- (−)-epicatechin-3-gallate (ECG).

EGCC is the most active catechin in green tea and has been widely researched. Laboratory studies, animal studies, and early phase clinical trials have found that EGCG may be highly active in blocking pathways that involve the growth of prostate cancer cells.

To make green tea, the tea leaves are roasted in a wok (or, historically, steamed) to preserve the catechins and retain freshness. Black tea is made using a process that causes the catechins and other compounds in the leaves to oxidize, producing darker colored tea. Oolong tea is made from partially oxidized leaves.

Some studies suggest that green tea may protect against cardiovascular disease and some types of cancer, including prostate cancer. Clinical trials designed to study whether green tea is useful in treating prostate cancer are in the early stages. There is not enough evidence to show whether green tea is effective in treating prostate cancer.

2. **How is green tea administered or consumed?**

Green tea may be consumed as a beverage or taken in dietary supplements.
3. **Have any preclinical (laboratory or animal) studies been conducted using green tea?**

Laboratory and animal research has been done to study the effects of green tea in prostate cancer.

Studies of green tea in the laboratory have shown the following:

- EGCG was shown to block the stimulating effect of androgen (a male sex hormone) on human prostate tumor cells, slow their spread, and increase cell death.
- Prostate cancer cells were treated with either EGCG or EGCG-loaded nanoparticles. While both treatments decreased cell spread and increased cell death, the nanoparticle treatment was more effective at lower levels, suggesting this type of delivery system for EGCG may make it easier for the body to use and improve EGCG's anticancer activity.
- Green tea polyphenols may cause anticancer effects by blocking histone deacetylases (HDAC) which are found in large amounts in cancer cells, including those in prostate cancer. Treating prostate cancer cells with green tea polyphenols lowered HDAC activity and caused cell death.

Studies of green tea in animal models of prostate cancer have shown the following:

- Strains of mice created to develop prostate cancer that acts like human cancer were given either plain water or water treated with green tea catechins (comparable to a human drinking 6 cups of green tea/day). After 24 weeks, the mice given plain water had developed prostate cancer while the mice given water with green tea catechins showed only prostatic intraepithelial neoplasia (PIN) lesions.
- In a study of EGCG, mice were implanted with prostate cancer cells and injected with EGCG or placebo 3 times/week. The mice that received the EGCG treatment had lower levels of proteins needed for androgen activity than those treated with placebo.
- In another study of EGCG, strains of mice created to develop prostate cancer that acts like human cancer were given EGCG in drinking water (comparable to a human drinking 6 cups of green tea/day) starting at either 12 weeks of age or 28 weeks of age. EGCG treatment prevented high-grade PIN lesions in mice that began treatment at 12 weeks but not in those that began treatment at 28 weeks of age.
- In a study of green tea polyphenols, these strains of mice were given polyphenols in drinking water starting at different ages (to match different stages of prostate cancer). All the green tea-fed mice were tumor-free longer than water-fed control mice, and the mice that were fed with green tea the earliest benefitted the most.
- In another study of green tea polyphenols, these strains of mice were fed polyphenols by mouth (comparable to a human drinking 6 cups of green tea/day). As measured by MRIs over time, tumor development was delayed and tumor growth was slowed in the polyphenol-fed mice compared to water-fed mice. In addition, the polyphenols caused high levels of cell death, possibly limiting the spread of cancer to distant parts of the body.
- Safety studies of Polyphenon E (a green tea extract with a mixture of catechins) have been done in dogs given various doses by mouth. The green tea extract caused more harmful side effects in fasting dogs compared to fed dogs.
- Polyphenon E was studied to find whether it prevents the spread of prostate cancer tumors. Mice created to develop prostate cancer that acts like human cancer were fed high-dose Polyphenon E. Both the number and size of prostate cancer tumors in mice treated with Polyphenon E were markedly lower than in untreated mice. Safety studies of Polyphenon E in mice found no harmful side effects.

4. **Have any clinical trials (research studies with people) of green tea been conducted?**

Population studies and clinical trials have been done to find out if green tea may be useful in preventing or treating prostate cancer.

**Population studies**

Population studies look for risk factors and ways to control disease in large groups of people.
A review of many population studies combined, mainly from Asia, showed mixed findings about whether green tea had a protective effect or no effect on prostate cancer risk. Many factors may be involved in these mixed results, including study location, tobacco and alcohol use, and other dietary differences. Black tea was not found to affect prostate cancer risk.

Overall, population studies suggest that green tea may help protect against prostate cancer in Asian populations. Prostate cancer deaths there are among the lowest in the world. As more people drink green tea worldwide, including in the United States, further population studies will add to information about whether green tea or green tea catechins may help protect against prostate cancer.

**Clinical trials of preventing prostate cancer**

In 2 randomized clinical trials in men with high-grade prostatic intraepithelial neoplasia (HGPIN), those treated with green tea catechins had lower rates of developing prostate cancer than those treated with a placebo. The findings suggest that green tea catechins may lower the risk of prostate cancer in patients at high risk for the disease.

**Clinical trials of treating prostate cancer**

Clinical trials designed to study whether green tea is useful in treating prostate cancer have shown the following:

Patients scheduled to undergo radical prostatectomy were assigned to drink green tea, black tea, or soda five times/day for 5 days. Bioavailable tea polyphenols were found in prostate tissue samples of patients who drank either green tea or black tea. In addition, prostate cancer cells treated with blood taken from patients after they drank tea grew and divided more slowly than cells treated with blood taken from patients before they drank tea.

Fifty patients scheduled to undergo radical prostatectomy were assigned to take Polyphenon E (800 mg EGCG) or a placebo daily for 3 to 6 weeks. Patients treated with Polyphenon E had lower blood levels of prostate specific antigen (PSA) and insulin-like growth factor-1 (a protein linked with increased risk of prostate cancer) than patients treated with placebo, but these differences were not meaningful. The findings suggest that the possible anticancer effects of green tea polyphenols may need to be studied in longer treatment trials.

Patients scheduled to undergo radical prostatectomy were assigned to drink either green tea, black tea, or water on a daily basis. In this study, only the men drinking green tea showed a small but notable decrease in PSA levels.

A small group of hormone-refractory prostate cancer patients were given capsules of green tea extract (375 mg total polyphenols/day) for up to 5 months. The study showed that the green tea treatment was well tolerated by most of the patients. However, no patient had a meaningful decrease in PSA levels and all 19 patients had disease progression within 1 to 5 months.

Patients with androgen-independent prostate cancer that had spread to other places in the body consumed powdered green tea extract (6 grams/day for up to 4 months). Of the forty-two participants, one had a meaningful decrease in blood PSA levels which did not last longer than 2 months. Green tea extract was well tolerated by most of the study patients. However, there were 6 reports of serious side effects, including insomnia, confusion, and fatigue. The findings suggest that green tea extract may have limited benefits in patients with advanced prostate cancer.

5. **Have any side effects or risks been reported from green tea?**

Phase I/II clinical studies have shown that EGCG in doses up to 1000 mg a day for up to a year is absorbed and used by the body with few side effects. A trial of oral green tea extract in patients with solid tumors reported that a safe dose was equal to 7-8 cups (120 ml/cup) of tea 3 times a day for 6 months. Side effects were found to be caused by the caffeine and not the EGCG.

Four phase I studies of Polyphenon E in single doses or multidoses were done in healthy volunteers. Polyphenon E was given in a range of doses and found to be well tolerated. Side effects were generally mild, with no serious side effects reported. The most frequently reported side effects thought to be related to the drug include headache, nausea, abdominal pain, diarrhea, upset stomach, dizziness, and weakness. Gastrointestinal side effects were usually mild, occurring most often in patients taking the drug on an empty stomach and at the
highest doses.

In safety studies of patients with prostate cancer, short-term green tea use for up to 90 days was well tolerated. One study found that the most commonly reported side effects of green tea were gastrointestinal symptoms. These were mild except for two reports of severe anorexia and moderate breathing problems.

Clinical trials have reported on the safety of long-term use of green tea compounds for the prevention of prostate cancer. In a United States trial, men at risk of prostate cancer were given 400 mg of Polyphenon E or a placebo for 1 year. There were more possible side effects reported in the group receiving the Polyphenon E than in the group receiving the placebo.

The FDA Division of Drug Oncology Products recommends that Polyphenon E should be taken with food by patients in clinical trials and that liver function tests should be considered during treatment.

Various types and doses of green tea extracts taken by mouth have been linked with several cases of liver damage in recent years. Most of those affected were women and many were taking green tea extract for weight loss. Most patients recovered within 4 months after stopping the green tea extract. However, there is one case report of acute liver failure in a woman who then needed a liver transplant. Her doctors concluded that her condition was likely caused by over-the-counter green tea extract capsules for weight loss.

6. Is green tea approved by the U.S. Food and Drug Administration (FDA) for use as a cancer treatment in the United States?

The U.S. Food and Drug Administration has not approved the use of green tea as a treatment for cancer or any other medical condition.

Green tea is available in the United States in food products and dietary supplements. Dietary supplements are products meant to be added to the diet. They are not drugs and are not meant to treat, prevent, or cure diseases. The manufacturer is responsible for ensuring that the product is safe and that the label claims are truthful and not misleading. The FDA does not approve dietary supplements as safe or effective before they are sold.

Current Clinical Trials

Check the list of NCI-supported cancer clinical trials for CAM clinical trials on green tea for prostate cancer and green tea extract for prostate cancer that are actively enrolling patients.

General information about clinical trials is also available from the NCI website.

Questions and Answers About Lycopene

1. What is lycopene?

Lycopene is a carotenoid (a natural pigment made by plants). It is red in color and tends to combine with or dissolve in fats. Lycopene protects plants from light-related stress and helps them use the energy of the sun to make nutrients. Lycopene is found in fruits and vegetables like tomatoes, apricots, guavas, and watermelons.

The main source of lycopene in the American diet is tomato-based products. Lycopene is more bioavailable (easier for the body to use) in processed tomato products like tomato paste and tomato puree than in raw tomatoes.

Lycopene has been studied for its role in cardiovascular disease and cancer. Population studies of lycopene in the diet suggest that it may help prevent cardiovascular disease through its effects on cholesterol, but some studies show mixed results.

Laboratory and animal studies have shown that lycopene may help lower the risk of prostate, skin, breast, lung, and liver cancers. However, population studies have found very limited evidence that consuming tomato products or lycopene lowers the risk of cancer.

2. How is lycopene administered or consumed?

Lycopene may be consumed in the diet or taken in dietary supplements.
3. Have any preclinical (laboratory or animal) studies been conducted using lycopene?

Laboratory research and animal studies have been done to find out if lycopene may be useful in preventing or treating prostate cancer.

Studies of lycopene in the laboratory have shown the following:

- Prostate cancer cells treated with lycopene had changes in their cell division cycle, leading to less cancer cell growth.
- In prostate cancer cells treated with lycopene, cholesterol levels were lower, leading to less cancer cell growth & more cancer cell damage.
- Treating prostate cancer cells with lycopene may change the way androgen (male hormone) is taken up and used in the cells, causing less cancer cell growth.
- Combining lycopene with standard cancer drugs may help stop the spread of different types of prostate cancer cells more than when drugs are used alone.

Studies of animal models of prostate cancer treated with lycopene have shown the following:

- Strains of mice created to develop prostate cancer that acts like human cancer were fed a diet with either lycopene beadlets or tomato paste. Mice on the lycopene beadlet diet had a greater decrease in prostate cancer rates than mice on the tomato paste diet. This suggests that lycopene might have more cancer protective effects than tomato paste.
- Combining lycopene with a substance found in dried tomatoes (FruHis) slowed the growth of prostate cancer cells in rats more than either lycopene or FruHis alone.
- A study of mice injected with human prostate cancer cells showed that mice treated with either lycopene or beta carotene supplements had less tumor growth.
- A study of mice injected with human prostate cancer cells and treated with a certain chemotherapy drug, lycopene, or both showed that those treated with chemotherapy and lycopene lived longer and had smaller tumors than those treated with chemotherapy alone.

4. Have any population studies or clinical trials (research studies with people) of lycopene been conducted?

Several population studies and clinical trials have been done to find out if lycopene may be useful in preventing or treating prostate cancer.

**Population studies**

Population studies look for risk factors and ways to control disease in large groups of people. Population studies of prostate cancer risk have shown the following mixed results:

- Population studies in men have found that high amounts of lycopene in the diet are linked with a lower risk of developing prostate cancer.
- Some studies have shown that lycopene levels in the blood and tissue of patients with cancer are lower than in those who do not have cancer. However, other studies have not shown this.
- A 2013 review of several studies combined found that men who ate large amounts of raw or cooked tomatoes may have a slightly lower risk of prostate cancer.
- A study found no link between lycopene and tomatoes in the diet and prostate cancer risk in the overall population. However, in men with a family history of the disease, higher amounts of lycopene in the diet were linked with a lower risk of prostate cancer. Another study in the same group of men found no difference in blood levels of lycopene between healthy men and men who developed prostate cancer.

Many issues may be involved in these mixed findings, including sources and types of lycopene, other dietary differences, obesity, tobacco and alcohol use, and genetic risk factors. Most research has studied the effects of lycopene on the risk of all prostate cancers, and has not studied effects of lycopene on low-grade compared with
Clinical trials of prevention or treatment of early prostate cancer

Clinical trials designed to study whether lycopene is useful in preventing or treating early prostate cancer have shown the following:

- Men with benign prostate hyperplasia (BPH) or prostate cancer were given tomato sauce dishes for 3 weeks before scheduled surgery to remove the prostate. The study found that they had markedly lower prostate specific antigen (PSA) levels and more cancer cell death found in the prostate when examined after surgery than a similar group of patients who did not receive the tomato sauce dishes.

- A study of 40 men with high-grade prostatic intraepithelial neoplasia (HGPIN) who took lycopene supplements for 2 years had a greater decrease in PSA levels than those who did not. During follow-up, adenocarcinomas were diagnosed more often in patients who did not take the supplements. This indicated that lycopene may be useful in preventing HGPIN from developing into prostate cancer.

- In another study of men at high risk of prostate cancer (such as men with HGPIN), those who took a daily multivitamin with no lycopene and those who took the same multivitamin plus lycopene daily for 4 months showed no difference in PSA levels.

There are other trials of combination therapies that include lycopene in the Combination Therapies section of this summary.

Clinical trials of treating prostate cancer

Clinical trials designed to study whether lycopene is useful in treating prostate cancer have shown the following:

- Men with prostate cancer that had not spread were given lycopene supplements for 3 weeks before surgery to remove the prostate. Those who received lycopene supplements had smaller tumors and lower PSA levels than those who did not. This study suggests that lycopene may be helpful in treating prostate cancer. Another study of men with prostate cancer that had not spread showed that men who took lycopene supplements for 1 year had lower PSA velocity (a measure of how fast PSA levels in the blood increase over time) after treatment.

- Men who had biochemical relapse of prostate cancer (a rise in the blood level of PSA after treatment with surgery or radiation) were given different doses of lycopene supplements for 1 year. Study results showed that lycopene seemed safe & had no side effects, but did not change PSA levels in biochemically relapsed prostate cancer.

- Men with hormone-refractory prostate cancer (HRPC) (tumors that do not respond to treatment with hormones) were given lycopene supplements for periods of 3 or 6 months in 2 different studies. These studies showed mixed results in lowering PSA levels in men with HRPC.

- A study was done in 46 men with androgen-independent prostate cancer (tumors that do not need androgen to grow) who consumed lycopene in either tomato paste or tomato juice daily for 4 months. Results showed that only one patient had a lower PSA level. Several men reported gastrointestinal side effects after consuming tomato paste or tomato juice.

There are other trials of combination therapies that include lycopene in the Combination Therapies section of this summary.

5. Have any side effects or risks been reported from lycopene?

Lycopene has been consumed in many clinical trials with very few side effects by men at high risk for prostate cancer and by prostate cancer patients. Patients have had only occasional gastrointestinal symptoms (e.g. diarrhea, nausea and vomiting, bloating, gassiness and stomach irritation). In one study, symptoms went away when lycopene was taken with meals.

6. Is lycopene approved by the U.S. Food and Drug Administration (FDA) for use to prevent or treat cancer in the United States?
The U.S. Food and Drug Administration has not approved the use of lycopene as a treatment for cancer or any other medical condition.

Lycopene is available in the United States in food products and dietary supplements. Dietary supplements are products meant to be added to the diet. They are not drugs and are not meant to treat, prevent, or cure diseases. The manufacturer is responsible for ensuring that the product is safe and that the label claims are truthful and not misleading. The FDA does not approve dietary supplements as safe or effective before they are sold.

Current Clinical Trials

Check the list of NCI-supported cancer clinical trials for CAM clinical trials on lycopene for prostate cancer that are actively enrolling patients.

General information about clinical trials is also available from the NCI website.

Questions and Answers About Modified Citrus Pectin

1. What is modified citrus pectin?

Pectin is a type of polysaccharide (a carbohydrate with many small sugar molecules that are chemically linked). Pectin is found in the cell walls of most plants and has gel-like qualities that are useful in making many types of food and medicine.

Citrus pectin is found in the peel and pulp of citrus fruits such as oranges, grapefruit, lemons, and limes. Citrus pectin can be modified with high pH and heat to break its molecules into smaller pieces. Modified citrus pectin (also called MCP) can be digested and absorbed by the body.

2. How is MCP administered or consumed?

MCP may be taken by mouth in powder or capsule form.

3. Have any preclinical (laboratory or animal) studies been conducted using MCP?

A study in prostate cancer cells compared 3 different kinds of pectin: citrus pectin, PectaSol (a dietary supplement with MCP), and fractionated pectin powder. Prostate cancer cells treated with the pectin powder had more damage than those treated with citrus pectin or PectaSol. However, when citrus pectin was modified by heating it, it caused the same amount of damage to prostate cancer cells as the pectin powder.

Only a few studies have reported the effects of MCP in animal models of cancer, including one prostate cancer study. Rats injected with prostate cancer cells and treated with MCP showed less spread of the cancer to the lungs but no effect on tumor growth at the original cancer site.

4. Have any population studies or clinical trials (research studies with people) of MCP been conducted?

A few studies in prostate cancer patients suggest that MCP may have some anticancer benefits.

In a study of patients with advanced solid tumors, including prostate cancers, MCP powder in water was given 3 times/day for at least 8 weeks. The study showed some quality of life improvements in physical functioning, overall health, fatigue, pain, and insomnia. About one-fourth of patients showed stable disease after 8 weeks of treatment and a smaller number had stable disease for more than 24 weeks. Since the study did not include a group of patients who did not receive MCP for comparison, it was not designed to be able to tell if any of these changes were due to the addition of MCP. The primary goal of the study was to determine if MCP would be well tolerated by cancer patients, and it was.

In a study of the effect of MCP on prostate-specific antigen (PSA) doubling time (how long it takes PSA levels in the blood to increase by 100 percent), prostate cancer patients who had rising PSA levels were given 6 PectaSol capsules 3 times/day for 12 months. After treatment, 7 out of 10 patients showed a slowing of PSA doubling time.

5. Have any side effects or risks been reported from MCP?

Two studies of MCP showed that most patients had very few side effects. Itching, stomach upset, and gassiness...
were reported in one study. In another study, 3 patients had abdominal cramps and diarrhea that went away when their treatment was stopped.

6. **Is MCP approved by the U.S. Food and Drug Administration (FDA) for use to prevent or treat cancer in the United States?**

The U.S. Food and Drug Administration has not approved the use of MCP as a treatment for cancer or any other medical condition.

MCP is available in the United States in food products and dietary supplements. Dietary supplements are products meant to be added to the diet. They are not drugs and are not meant to treat, prevent, or cure diseases. The manufacturer is responsible for ensuring that the product is safe and that the label claims are truthful and not misleading. The FDA does not approve dietary supplements as safe or effective before they are sold.

## Current Clinical Trials

Check the list of NCI-supported cancer clinical trials for CAM clinical trials on modified citrus pectin for prostate cancer that are actively enrolling patients.

General information about clinical trials is also available from the NCI website.

## Questions and Answers About Pomegranate

1. **What is pomegranate?**

The pomegranate fruit (Punica granatum L.) is native to Asia and grown throughout the Mediterranean, Southeast Asia, East Indies, Africa, and the United States. Pomegranate has been used for medicinal purposes since ancient times.

Different parts of the pomegranate fruit have bioactive compounds (chemicals found in small amounts that have actions in the body that may promote good health). These include:

   - The peel, which makes up half the fruit and contains minerals and other bioactive compounds.
   - The seeds.
   - The aril (outer layer surrounding the seeds), which contains phenolics and flavonoids including anthocyanins, which give the pomegranate fruit and juice their red color.

2. **How is pomegranate administered or consumed?**

Pomegranate may be consumed in the diet or taken in dietary supplements.

3. **Have any preclinical (laboratory or animal) studies been conducted using pomegranate?**

Laboratory studies of pomegranate in cancer cell lines include the following:

   - A study of 13 pomegranate compounds showed some were able to slow the growth and spread of prostate cancer cells and to cause cell death. Higher doses were found to be more effective. Punicic acid (a bioactive compound found in pomegranate seeds) was shown to have the strongest effect in causing cell death.

   - Three types of prostate cancer cell lines were treated with either pomegranate extract, pomegranate juice, or two of their bioactive compounds. All pomegranate treatments were shown to increase cell death and decrease the spread of cancer cells, with higher doses found to be more effective. In the cell line that was dependent on androgen (male hormone) for growth, all treatments affected the way androgen was taken up and used.

   - Other studies in cancer cell lines found that the anticancer activity of pomegranate included effects on certain enzymes and pathways, such as the insulin-like growth factor (IGF) system.

Studies of animal models of prostate cancer in which the animals were given pomegranate have shown the following:
A study of mice injected with prostate tumor-forming cells found that mice that drank pomegranate extract in water had tumors that were smaller and took longer to develop than tumors in mice that drank normal water.

In a study of strains of mice created to develop prostate cancer that acts like human cancer, all mice that were given normal water for 28 weeks developed tumors. Only one-fifth to one-third of the mice that received pomegranate extract in water developed tumors, with the mice that received the highest amounts of pomegranate extract having the fewest tumors.

4. Have any clinical trials (research studies with people) of pomegranate been conducted?

Three clinical trials studied the effect of pomegranate products on prostate-specific antigen doubling time (PSADT) in patients with recurrent prostate cancer who had rising PSA levels after surgery or radiation therapy.

In a phase II study reported in 2006, 48 patients were given 8 ounces of pomegranate juice daily for up to 33 months. Drinking pomegranate juice was related to a slowing of PSA doubling time (how long it takes PSA levels in the blood to increase by 100 percent).

In a phase II study reported in 2013, patients were given 1 gram or 3 gram doses of pomegranate extract. Both doses of pomegranate extract (equal to either 8 ounces or 24 ounces of pomegranate juice) were related to a slowing of PSA doubling time. Results were similar in patients who received either the low dose or high dose of pomegranate extract.

In a phase III placebo-controlled clinical trial reported in 2015, 183 patients were given either pomegranate juice, pomegranate extract, or a placebo. The study found no meaningful difference in the PSA doubling time for the 3 groups.

These studies differed in PSA levels of the patients enrolled and whether there was a placebo group. All three trials found that pomegranate extract was safe to consume. Further studies may be able to show whether patients with certain genetic markers will benefit from pomegranate products.

5. Have any side effects or risks been reported from pomegranate?

Two studies of pomegranate juice in either prostate cancer patients or patients with erectile dysfunction reported no serious side effects.

6. Is there any reason people should avoid pomegranate juice?

Some pomegranate products may contain added sugar. Certain groups, such as the American Institute for Cancer Research (AICR), recommend avoiding sugary drinks. For more information, see the AICR website.

7. Is pomegranate approved by the U.S. Food and Drug Administration (FDA) for use to prevent or treat cancer in the United States?

The U.S. Food and Drug Administration has not approved the use of pomegranate as a treatment for cancer or any other medical condition.

Pomegranate is available in the United States in food products and dietary supplements. Dietary supplements are products meant to be added to the diet. They are not drugs and are not meant to treat, prevent, or cure diseases. The manufacturer is responsible for ensuring that the product is safe and that the label claims are truthful and not misleading. The FDA does not approve dietary supplements as safe or effective before they are sold.

Current Clinical Trials

Check the list of NCI-supported cancer clinical trials for CAM clinical trials on pomegranate-extract pill for prostate cancer, pomegranate juice for prostate cancer, and pomegranate liquid extract for prostate cancer that are actively enrolling patients.

General information about clinical trials is also available from the NCI website.

Questions and Answers About Selenium
1. **What is selenium?**

Selenium is a trace mineral (a nutrient that is essential to humans in tiny amounts). Selenium is found in certain proteins that are active in many body functions, including reproduction and immunity. Food sources of selenium include meat, vegetables, and nuts. The amount of selenium found in the food depends on the selenium content of the soil where the food grows. Selenium is stored in the thyroid gland, liver, pancreas, pituitary gland, and kidneys.

Selenium is found in an enzyme called glutathione peroxidase which acts as an antioxidant. However, in high amounts, selenium may act as a pro-oxidant (a substance that can make oxygen byproducts that may damage cells).

Selenium may play a role in many diseases, including cancer. Animal and population studies have suggested that supplementing the diet with selenium may lower the risk of cancer. Results from the Nutritional Prevention of Cancer Trial (NPC) showed that, although selenium supplements did not affect the risk of skin cancer, they markedly lowered the rates of lung, colorectal, and prostate cancer. However, studies of how selenium levels in the blood affect the risk of developing of prostate cancer have shown mixed results. Results of the large National Cancer Institute-sponsored Selenium and Vitamin E Cancer Prevention Trial (SELECT) caution against the use of selenium supplements among men with prostate cancer, and other studies have concluded that men should avoid selenium supplementation at doses that are higher than the recommended dietary intake.

2. **How is selenium administered or consumed?**

Selenium may be consumed in the diet or taken in dietary supplements. For adults, the recommended daily allowance for selenium is 55 µg/day.

3. **Have any preclinical (laboratory or animal) studies been conducted using selenium?**

Laboratory studies to find out if selenium may be useful in preventing or treating prostate cancer have shown the following:

- Different forms of selenium have been shown to slow the growth and spread of prostate cancer cells.
- Selenium nanoparticles may be less toxic to normal tissues than other selenium compounds.

Studies of selenium in animal models of prostate cancer have shown the following:

- A study in mice looked at the effect of dietary selenium on prostate cancer prevention starting at different ages. Adult mice and younger mice were fed selenium-enriched diets or diets with no selenium for 6 months or 4 weeks and then injected with human prostate cancer cells. Adult mice with selenium in their diets developed fewer tumors than adult mice with diets lacking in selenium. However, in younger mice, dietary selenium had no effect on tumor development.
- Strains of mice which developed prostate cancer that acts like human cancer were treated with 2 forms of selenium, MSeA and methylselenocysteine (MSeC), or water only. In the selenium-treated mice, growth of precancerous lesions was slowed and cancer cell death was increased compared to the water-treated mice. MSeA treatment also increased survival time of the study mice. The mice that received MSeA treatment starting at 10 weeks of age had less aggressive prostate cancer than did mice starting treatment at 16 weeks of age, suggesting early treatment with MSeA may be more effective than later treatment.

4. **Have any population studies or clinical trials (research studies with people) of selenium been conducted?**

Population studies and clinical trials have been done to find out if selenium may be useful in preventing or treating prostate cancer.

**Population studies**

Population studies look for risk factors and ways to control disease in large groups of people.

Studies of how selenium levels in the blood affect the risk of developing of prostate cancer have shown mixed results. One study tracking subjects for up to 10 years found that men with higher levels of selenium in their blood had a lower risk of prostate cancer. Another study found that prostate cancer patients had lower whole...
blood selenium levels than did healthy men. However, a 2009 study of prostate cancer patients found that men with higher selenium levels in their blood were at greater risk of being diagnosed with aggressive prostate cancer. These differences may be due to genetic variations among individual patients.

**Clinical trials of preventing/treating prostate cancer**

Clinical trials of the effects of selenium on prostate specific antigen (PSA) levels or the development of prostate cancer have shown mixed results, including the following:

- In a study reported in 2013, men at high risk for prostate cancer were given either daily doses of high-selenium yeast (200 µg or 400 µg) or a placebo for up to 5 years. There were no differences in prostate cancer rates or PSA velocity in men who took the selenium supplement compared to those who took the placebo.

- In an earlier study, men with high-grade prostatic intraepithelial neoplasia (HGPIN) were given either a selenium supplement (200 µg/ day) or a placebo for 3 years or until they were diagnosed with prostate cancer. The results suggested that selenium supplements had no effect on prostate cancer risk.

- Sixty men were given either a selenium glycinate supplement (200 µg/ day) or a placebo for 6 weeks. Blood samples were collected at the start and the end of the study. Compared to the placebo group, men who received selenium supplements showed higher activity of two selenium enzymes in their blood and lower levels of PSA at the end of the study.

- The Health Professionals Follow-Up Study included 4,459 men diagnosed with prostate cancer that had not spread. The study found that taking selenium supplements (140 or more μg/ day) after diagnosis may increase the risk of death from prostate cancer and recommended that men with prostate cancer use caution in taking selenium supplements.

**The Selenium and Vitamin E Cancer Prevention Trial (SELECT)**

The Selenium and Vitamin E Cancer Prevention Trial (SELECT) was a large clinical trial begun by the National Institutes of Health in 2001 to study the effects of selenium and/or vitamin E on the development of prostate cancer. Over 35,000 men, aged 50 years and older, were randomly assigned to receive one of the following combinations daily for 7-12 years:

- Vitamin E (alpha-tocopherol acetate, 400 IU/ day) and a placebo;
- Selenium (L-selenomethionine, 200 mcg/ day) and a placebo;
- Vitamin E and selenium; or
- Two placebos.

First results of SELECT reported in 2009 found no meaningful difference in the rate of prostate cancer among the 4 groups. In the Vitamin E alone group, there was a slight increase in the rate of prostate cancer and in the selenium alone group, there was a slight increase in the rate of diabetes. Even though these changes were not clearly shown to be due to the supplement, the men in the study were advised to stop taking the study supplements.

Updated results of SELECT in 2011 showed that selenium supplements had no meaningful effect on prostate cancer risk; however, men taking vitamin E alone had a 17% increase in prostate cancer risk compared to men in the placebo group.

In 2014, further results of SELECT showed that selenium supplements in men with low selenium levels at the start of the trial had no effect on prostate cancer risk; however, selenium supplements in men who had high levels of selenium at the start of the trial increased the risk of high-grade prostate cancer.

Several factors may have affected study results, including the dose of vitamin E chosen and the form of selenium used. The authors concluded that men should avoid selenium supplementation at doses that are higher than the recommended dietary intake.

A cohort study of 1,434 men enrolled in SELECT suggested that variations in certain genes which control the
ways selenium and vitamin E are processed by the body may have an effect on the risk of prostate cancer, including high-grade prostate cancer.

5. Are there any risks in taking selenium supplements, and have any side effects been reported?

Selenium supplements have been well tolerated in many clinical trials. Patients are closely monitored and given specific doses in clinical trials within the study criteria. In two published trials, there were no differences reported in adverse effects between placebo or treatment groups. However, in the SELECT trial, the use of selenium supplements (L-selenomethionine, 200 µg daily) was linked with a slight increase in the rate of diabetes mellitus.

6. Is selenium approved by the U.S. Food and Drug Administration (FDA) for use as a cancer treatment in the United States?

The U.S. Food and Drug Administration has not approved the use of selenium supplements for the treatment or prevention of cancer or any other medical condition.

Selenium is available in the United States in food products and dietary supplements. Dietary supplements are products meant to be added to the diet. They are not drugs and are not meant to treat, prevent, or cure diseases. The manufacturer is responsible for ensuring that the product is safe and that the label claims are truthful and not misleading. The FDA does not approve dietary supplements as safe or effective before they are sold.

Current Clinical Trials

Check the list of NCI-supported cancer clinical trials for CAM clinical trials on selenium for prostate cancer that are actively enrolling patients.

General information about clinical trials is also available from the NCI website.

Questions and Answers About Soy

1. What is soy?

The soybean plant has been grown in Asia for food since ancient times. Soy first arrived in Europe and North America in the 18th century. The soybean can be processed into a wide variety of products including soy milk, miso, tofu, soy flour, and oil.

Soy foods contain many phytochemicals that may have health benefits. Isoflavones are the most widely researched compounds in soy. Major isoflavones in the soybean include genistein (which may be the most bioactive isoflavone), daidzein, and glycitein. Isoflavones protect the soybean plant from stress and have antioxidant, antimicrobial, and antifungal actions.

Isoflavones are phytoestrogens (estrogen-like substances found in plants) that attach to estrogen receptors in cells. Genistein has been shown to affect many pathways in prostate cancer cells involved in the growth and spread of cancer.

2. How is soy administered or consumed?

Soy may be consumed in the diet or taken in dietary supplements.

3. Have any preclinical (laboratory or animal) studies been conducted using soy?

Laboratory research and animal studies have been done to find out if soy may be useful in preventing or treating prostate cancer.

Studies of soy in the laboratory have shown the following:

- Several laboratory studies have found that treating human prostate cancer cells with isoflavones (such as genistein or daidzein) interferes with pathways in prostate cancer cells related to inflammation and cancer growth and spread.
- Some laboratory studies have found that treating prostate cancer cells with whole soy extract (containing
all the major isoflavones) or combining other plant-based compounds with isoflavones may have more anticancer effects than using single isoflavones. One study compared treating human prostate cancer cells with soy isoflavones, curcumin (a yellow pigment of the spice turmeric that is being studied in cancer prevention), or a combination of the two compounds. Results showed that combining curcumin and isoflavones was more effective in lowering prostate-specific antigen (PSA) levels than using either compound alone.

Studies of animal models of prostate cancer treated with soy have shown the following mixed results:

- Strains of mice created to develop prostate cancer that acts like human cancer were fed a diet with genistein or a control diet. Compared with mice on the control diet, the mice fed the genistein diet had less prostate cancer cell growth and lower levels of growth promoting proteins.
- A study of mice that were genetically modified to produce prostate cancer found that mice fed a low-dose genistein diet had more spread of cancer than mice fed either a high-dose genistein diet or a diet with no genistein. This suggests that the effects of genistein on prostate cancer may vary depending on dose and on how early it is given.
- A study in mice implanted with advanced human prostate cancer found that those given daily genistein in peanut oil developed more tumors in other parts of the body than mice given peanut oil without genistein.
- In a study of combining radiation therapy with soy isoflavones, mice implanted with prostate cancer cells were treated with genistein, mixed isoflavones (genistein, daidzein, and glycitein), and/or radiation. Mixed isoflavones were found to be more effective than genistein in slowing prostate tumor growth. Combining mixed isoflavones with radiation was found to be most effective in slowing tumor growth.

4. Have any population studies or clinical trials (research studies with people) of soy been conducted?

Many population studies and clinical trials have been done to find out if soy may be useful in preventing or treating prostate cancer. Soy products studied include dietary supplements, drinks, and bread.

**Population studies**

Population studies look for risk factors and ways to control disease in large groups of people. Population studies of soy intake and prostate cancer risk have shown the following mixed results:

- A 2009 review of many studies combined showed that men eating large amounts of nonfermented soy foods (for example, tofu and soybean milk) had a lower risk of prostate cancer. Eating large amounts of fermented foods (for example, miso) was not found to affect the risk of prostate cancer.
- A 2013 review showed that PSA levels and sex hormone levels were not markedly different in men treated with soy, compared with men who were not treated with soy.

**Clinical trials of preventing prostate cancer**

- In a study of Japanese men who underwent a prostate biopsy but who did not have cancer, some received a daily supplement of soy isoflavones (40 mg) and curcumin (100 mg), while others received a placebo. After 6 months, there were no differences in PSA levels between the supplement group and the placebo group overall. However, among patients with higher PSA levels at the start, those who received the supplement had meaningful decreases in PSA levels compared to patients in the placebo group.
- A study was done to find out if a soy diet standard in Asia would be practical for European men to follow. Healthy men ate either a high-soy (2 daily soy servings) or low-soy (usual) diet for 3 months, then crossed over to the other diet. Lower PSA levels were seen with the high-soy diet. Results showed that study volunteers were able to follow the high-soy diet.
- Men at risk for prostate cancer or with low-grade prostate cancer were given either soy protein, alcohol-washed soy protein (which is lower in isoflavones), or milk protein (which has no isoflavones) for 6 months. PSA levels did not differ among the groups at 3 months or 6 months. Fewer cases of prostate cancer were found after 6 months in men who consumed either type of soy protein than in men who consumed milk protein.
Clinical trials of treating prostate cancer

- In a trial of soy isoflavones, prostate cancer patients with rising PSA levels who had been treated with radiation therapy consumed a soy drink daily for 6 months. The soy drink contained 65-90 mg of isoflavones. Results showed that the soy drink had very few side effects and slowed PSA doubling time (how long it takes PSA levels in the blood to increase by 100 percent). These findings indicate that consuming the soy drink may have helped slow the progression of prostate cancer.

- In a trial of genistein (a major isoflavone), prostate cancer patients scheduled for radical prostatectomy received either a placebo or genistein (30 mg/day) for 3-6 weeks before surgery. PSA levels in patients who received genistein decreased slightly while PSA levels in those who received the placebo increased slightly.

- In a trial of soy isoflavone, prostate cancer patients scheduled for prostatectomy received either capsules (containing 80 mg/day of isoflavones) or a placebo for up to 6 weeks before surgery. There was no difference in PSA, testosterone, or cholesterol level changes between the two groups.

- A trial of a soy protein supplement (containing 60 mg/day of isoflavones) studied patients with early-stage prostate cancer. Those who received the supplement for 12 weeks had slightly greater decreases in PSA and testosterone levels than those who received placebo.

- Trials of whole soy were done in men scheduled for surgery to remove the prostate. In one study, patients given soy supplements for 2 weeks before surgery showed much higher levels of isoflavones in prostate tissue than in blood. In another study, patients who ate high-phytoestrogen bread (containing soy or soy and linseed) had greater decreases in PSA levels than those who ate wheat bread.

- Two trials of a soy isoflavone supplement were done in prostate cancer patients receiving antiandrogen therapy. Side effects of antiandrogen therapy may include sexual dysfunction, lower quality of life, and changes in mental functioning. In both studies, men who received the isoflavone supplement (160 mg/day) for 12 weeks showed no improvement in side effects of antiandrogen therapy compared to men who received a placebo.

5. Have any side effects or risks been reported from soy?

Soy products and isoflavones have been consumed by prostate cancer patients with very few side effects in many clinical trials. The most commonly reported side effects were minor gastrointestinal symptoms.

6. Is soy approved by the U.S. Food and Drug Administration (FDA) for use to prevent or treat cancer in the United States?

The U.S. Food and Drug Administration has not approved the use of soy as a treatment for cancer or any other medical condition.

Soy is available in the United States in food products and dietary supplements. Dietary supplements are products meant to be added to the diet. They are not drugs and are not meant to treat, prevent, or cure diseases. The manufacturer is responsible for ensuring that the product is safe and that the label claims are truthful and not misleading. The FDA does not approve dietary supplements as safe or effective before they are sold.

Current Clinical Trials

Check the list of NCI-supported cancer clinical trials for CAM clinical trials on soy isoflavones for prostate cancer and soy protein isolate for prostate cancer that are actively enrolling patients.

General information about clinical trials is also available from the NCI website.

Questions and Answers About Vitamin D

1. What is vitamin D?

Vitamin D (also called calcipotriol, cholecalciferol, or ergocalciferol) is a fat-soluble vitamin found in fatty fish, fish liver oil, eggs, and enriched dairy products.
Vitamin D has many actions in the body, including the following:

- Helps absorb calcium from food in the small intestine.
- Improves muscle strength and immune system function.
- Lowers inflammation.
- Maintains levels of calcium and phosphate in the blood.

Vitamin D is needed for bone growth and protects against osteoporosis in adults. Vitamin D level is usually checked by measuring the amount of 25-hydroxyvitamin D in the blood.

2. **What are the sources of vitamin D?**

Vitamin D is made naturally by the body when exposed to sunlight. Vitamin D may also be consumed in the diet or taken in dietary supplements.

3. **Have any preclinical (laboratory or animal) studies been conducted using vitamin D?**

Laboratory and animal research studies suggest that vitamin D may have effects on prostate cancer cells through various pathways.

Preclinical studies of vitamin D in prostate cancer have shown the following:

- A study of a form of vitamin D showed that it may prevent prostate cancer cells from sticking to endothelium, the thin layer of cells that lines the inside of blood vessels, lymph vessels, and body cavities.
- In a 2011 study, mice were fed a diet with adequate vitamin D or a diet lacking vitamin D and were then injected with prostate cancer cells into bone marrow or into soft tissues. The mice lacking vitamin D developed bone tumors that were larger and grew faster than the mice that had adequate levels of vitamin D. However, there was no difference in soft tissue tumors among mice with different vitamin D levels. Results of this study show that a lack of vitamin D is linked with growth of prostate cancer cells in bone but not in soft tissue.
- A study of vitamin D as adjuvant therapy (therapy to make other types of treatment more effective) combined it with cryotherapy (freezing). Mice injected with prostate cancer cells were treated with calcitriol with or without cryotherapy. Those who were treated with the combination of calcitriol and freezing had more cancer cell death and less cancer cell spread than those who were treated with either calcitriol alone or freezing alone.

4. **Have any population studies or clinical trials (research studies with people) of vitamin D been conducted?**

Many population studies and clinical trials have been done to find out if vitamin D may be useful in preventing or treating prostate cancer.

**Population studies**

Population studies look for risk factors and ways to control disease in large groups of people. Population studies of vitamin D and prostate cancer risk have shown the following mixed results:

- Vitamin D levels in patients with prostate cancer that had not spread were taken annually for 5 years. Throughout the course of the study, lack of vitamin D was a common finding among these patients.
- Another study in patients with prostate cancer suggested that medium or high levels of vitamin D in the blood may be linked with better outcomes than lower levels. These findings indicate that vitamin D levels may play a role in whether or not the disease will worsen and may be a factor in predicting outcome in prostate cancer patients.
- One thousand patients with prostate cancer and 1000 control patients in the Alpha-Tocopherol, Beta-Carotene Cancer Prevention Study were followed for up to 20 years. Results suggested that men with higher blood levels of vitamin D had a greater risk of developing prostate cancer than men with lower vitamin D levels.
In a case-cohort analysis from the Selenium and Vitamin E Cancer Prevention Trial (SELECT), men who had moderate blood levels of vitamin D (45–70 nmol/L) were found to have a markedly lower risk of aggressive prostate cancer than men who had either lower or higher levels of vitamin D.

Vitamin D from sunlight exposure has been studied for possible effects on prostate cancer rates. A 2006 study found that PSA levels rise at a slower rate during the spring and summer compared to other times of the year, suggesting this may be due to higher vitamin D levels during those months. Another study found that while men with low levels of sun exposure had increased risk of all prostate cancers, those with prostate cancer who had less sun exposure showed lower risk of advanced disease.

Geographic patterns of deaths in the United States from 1950 to 1994 showed that higher death rates from prostate cancer occurred in parts of the country with lower levels of UV radiation from sunlight. This effect is strongest in places more than 40 degrees north of the equator, where sunlight is weakest during the winter months. These findings support the theory that lack of vitamin D increases the risk for prostate cancer.

Reviews of many population studies combined

A 2008 review of 45 observational studies combined found no link between intake of vitamin D and prostate cancer risk.

A 2011 review of 25 studies combined found no link between either vitamin D in the diet or blood levels of vitamin D and the risk of prostate cancer.

A 2014 review of 21 studies combined found that high levels of vitamin D in the blood may be linked with a higher risk of prostate cancer. Many factors may affect these findings, since some studies propose men from higher income groups may have higher vitamin D levels and are more likely to get PSA testing, leading to higher rates of reported prostate cancer.

Clinical trials of treating prostate cancer

Clinical trials in patients with prostate cancer have shown the following:

- A clinical trial treated patients with prostate cancer that had recurred (come back) with calcitriol (the active form of vitamin D) and naproxen for 1 year. Results showed that the combination of calcitriol and naproxen was effective in slowing the rate of rising PSA levels in study patients, suggesting it may slow disease progression.

- In a 2010 study, patients with prostate cancer that did not respond to hormone therapy were treated with calcitriol and dexamethasone. The results indicated that while the treatment was well tolerated, it did not have an effect on PSA levels in the study patients.

- In a 2009 study, patients with locally advanced or metastatic prostate cancer were treated with vitamin D. The study reported that one in every 5 patients who took vitamin D had improved PSA levels, suggesting that vitamin D may be an effective therapy for patients with advanced prostate cancer.

5. Have any side effects or risks been reported from vitamin D?

Vitamin D can be toxic when taken at high doses (10,000 to 50,000 IU per day) over a period of many years. Taking high levels of Vitamin D can cause too much calcium to be absorbed through the intestines, leading to rapid increases in blood calcium levels. This condition is called hypercalcemia.

Signs and symptoms of hypercalcemia may include frequent and excessive urination, excessive thirst, poor kidney function, and calcium build-up in soft tissues. There may be effects on the brain including depression and anorexia.

In a group of 26 studies, Vitamin D was reviewed for safety, effectiveness, and whether it interacts with drugs used to treat prostate cancer and other tumors. Calcitriol was the most common form of vitamin D used in these studies. The reviewers found no adverse effects beyond those expected from high-dose calcitriol, and the risk of drug interactions was found to be low.
A number of studies looked at the safety and effectiveness of high-dose calcitriol combined with chemotherapy (docetaxel) to treat men with androgen-independent prostate cancer. No higher levels of toxicity were found compared to treatment with docetaxel alone.

6. Is vitamin D approved by the U.S. Food and Drug Administration (FDA) for use as a cancer treatment in the United States?

The U.S. Food and Drug Administration has not approved the use of vitamin D as a treatment for cancer or any other medical condition.

Vitamin D is available in the United States in food products and dietary supplements. Dietary supplements are products meant to be added to the diet. They are not drugs and are not meant to treat, prevent, or cure diseases. The manufacturer is responsible for ensuring that the product is safe and that the label claims are truthful and not misleading. The FDA does not approve dietary supplements as safe or effective before they are sold.

Current Clinical Trials

Check the list of NCI-supported cancer clinical trials for CAM clinical trials on vitamin D for prostate cancer that are actively enrolling patients.

General information about clinical trials is also available from the NCI website.

Questions and Answers About Vitamin E

1. What is vitamin E?

Vitamin E is a nutrient that may protect against chronic diseases such as cardiovascular disease. Vitamin E is being studied in the prevention of some types of cancer.

There are eight different forms of vitamin E: four tocopherols (alpha-, beta-, gamma-, and sigma-) and four tocotrienols (alpha-, beta-, gamma-, and sigma-). Compared with other tocopherols, alpha-tocopherol (the form of vitamin E commonly found in dietary supplements) is found in greater amounts in the body and is the most active. Most vitamin E in the diet comes from gamma-tocopherol. Food sources of vitamin E include vegetable oils, nuts, and egg yolks.

Many of the possible health benefits of Vitamin E may be from its antioxidant activity. Vitamin E is a powerful antioxidant that protects cell membranes from damage caused by free radicals. Vitamin E also has other functions involved in cell signaling pathways and gene expression.

2. How is vitamin E administered or consumed?

Vitamin E may be consumed in the diet or taken in dietary supplements.

3. Have any clinical trials (research studies with people) of vitamin E been conducted?

Population studies and clinical trials have been done to find out if vitamin E may be useful in preventing or treating prostate cancer.

Population studies

Population studies look for risk factors and ways to control disease in large groups of people. Population studies of vitamin E in prostate cancer risk have shown the following:

- The NIH-AARP Diet and Healthy Study studied whether vitamin E in supplements and in the diet of volunteers may prevent prostate cancer. After 5 years, no link between vitamin E supplements and prostate cancer risk was found. However, a lower risk of advanced prostate cancer was found in those who had high intakes of one form of vitamin E (gamma-tocopherol).

- In a 2010 study that measured blood levels of trace elements and vitamin E, those who had prostate cancer had markedly lower blood levels of vitamin E than those who did not have prostate cancer. In addition, those who had higher PSA levels had lower levels of vitamin E in their blood.
Blood levels of alpha-tocopherol and gamma-tocopherol and prostate cancer risk were studied in participants in the Prostate, Lung, Colorectal and Ovarian (PLCO) Screening Trial. Men with higher levels of alpha-tocopherol had lower rates of prostate cancer, but this was noted only in current smokers and those who had recently quit.

In a review of many studies combined involving 370,000 men from several countries, higher blood levels of alpha-tocopherol were linked with a lower risk of prostate cancer in all patients, not just smokers.

Clinical trials of preventing or treating prostate cancer

In the Physicians’ Health Study II, men received either vitamin E supplements (400 IU synthetic alpha-tocopherol taken every other day) and/or vitamin C supplements (500 mg synthetic ascorbic acid taken daily) and were followed for an average of 8 years. The overall rates of prostate cancer were very similar in the men who received vitamin E supplements and in those who did not, suggesting that vitamin E may not prevent prostate cancer. Furthermore, vitamin E did not have an effect on total cancer or death rates in these participants.

The Alpha-Tocopherol, Beta Carotene Cancer Prevention Study (ATBC) trial measured blood levels of alpha-tocopherol and dietary intake of vitamin E in men who were followed for up to 19 years. Findings showed no link between vitamin E in the diet and prostate cancer risk, but showed that higher levels of alpha-tocopherol in the blood may be linked with a lower risk for developing advanced prostate cancer.

Men in the ATBC trial who developed prostate cancer were studied to find out if serum alpha-tocopherol levels affected survival time. Higher serum alpha-tocopherol levels, at both time of diagnosis and at the 3-year time point, were linked with improved prostate cancer survival.

A 2011 study of men who took part in The Carotene and Retinol Efficacy Trial (CARET) found that, among those who were current smokers, higher levels of serum alpha-tocopherols and gamma-tocopherols were linked with lower risk of aggressive prostate cancer.

The Selenium and Vitamin E Cancer Prevention Trial (SELECT)
The Selenium and Vitamin E Cancer Prevention Trial (SELECT) was a large clinical trial begun by the National Institutes of Health in 2001 to study the effects of selenium and/or vitamin E on the development of prostate cancer. Over 35,000 men, aged 50 years and older, were randomly assigned to receive one of the following combinations daily for 7-12 years:

- Vitamin E (alpha-tocopherol acetate, 400 IU/ day) and a placebo;
- Selenium (L-selenomethionine, 200 mcg/ day) and a placebo;
- Vitamin E and selenium; or
- Two placebos.

First SELECT results reported in 2009 found no meaningful differences in rates of prostate cancer among the 4 groups. In the Vitamin E alone group, there was a slight increase in the rate of prostate cancer and in the selenium alone group, there was a slight increase in the rate of diabetes. Based on those findings, the men in the study were advised to stop taking the study supplements.

Updated SELECT results in 2011 showed that selenium supplements had no meaningful effect on prostate cancer risk; however, men taking vitamin E alone had a 17% increase in prostate cancer risk compared to men in the placebo group.

In 2014, further SELECT results showed that vitamin E supplements alone had no effect on prostate cancer risk in men with high levels of selenium at the start of the trial; however, vitamin E supplements increased the risk of low-grade and high-grade prostate cancer in men with lower levels of selenium at the start of the trial.

Several factors may have affected study results, including the dose of vitamin E chosen and the form of selenium used.

A cohort study of 1,434 men enrolled in SELECT suggested that variations in certain genes which control the
ways selenium and vitamin E are processed by the body may have an effect on the risk of prostate cancer, including high-grade prostate cancer.

4. Have any side effects or risks been reported from vitamin E?

Alpha-tocopherols are deemed Generally Recognized as Safe by the U.S. Food and Drug Administration. In the Physicians’ Health Study II, there were no marked differences in rates of gastrointestinal symptoms, fatigue, drowsiness, skin discoloration or rashes, or migraine between men who took vitamin E (400 IU every other day of alpha-tocopherol) and those who took a placebo. However, there was a higher number of hemorrhagic strokes in men who took vitamin E than in men who took a placebo. In the Alpha-Tocopherol, Beta Carotene Cancer Prevention Study Group, there was also an increase in hemorrhagic strokes among men in the group that took vitamin E (50 mg/ day of alpha-tocopherol).

Earlier results from the SELECT trial showed no marked differences in rates of less severe adverse effects (such as hair loss, inflamed skin, and nausea) in the groups that took vitamin E (400 IU/ day of all-rac-alpha-tocopherol) compared to the other treatment groups. Later follow-up of SELECT participants showed an increased risk of prostate cancer among men in the vitamin E alone group.

5. Is vitamin E approved by the U.S. Food and Drug Administration (FDA) for use as a cancer treatment in the United States?

The U.S. Food and Drug Administration has not approved the use of vitamin E as a treatment for cancer or any other medical condition.

Vitamin E is available in the United States in food products and dietary supplements. Dietary supplements are products meant to be added to the diet. They are not drugs and are not meant to treat, prevent, or cure diseases. The manufacturer is responsible for ensuring that the product is safe and that the label claims are truthful and not misleading. The FDA does not approve dietary supplements as safe or effective before they are sold.

Current Clinical Trials

Check the list of NCI-supported cancer clinical trials for CAM clinical trials on vitamin E for prostate cancer that are actively enrolling patients.

General information about clinical trials is also available from the NCI website.

Combination Therapies

Pomi-T (Pomegranate, Green Tea, Broccoli, and Turmeric)

Polyphenols are compounds found in many plants and give some flowers, fruits, and vegetables their color. Polyphenols have antioxidant activity that helps protect cells from damage caused by free radicals.

A food supplement (Pomi-T) that is high in polyphenols was studied in a group of men who had prostate cancer that had not spread. This supplement contained a combination of the following:

- Pomegranate whole fruit powder.
- Broccoli powder.
- Turmeric powder.
- Green tea extract.

These ingredients were raw, dry, plant-based powders that were not standardized (a standardized herbal supplement has one or more active ingredients measured in a specific amount, so that the product is the same from batch to batch).

In a randomized clinical trial, 199 men were given either Pomi-T or a placebo for 6 months. Before the study began, slightly less than half of the men had rising prostate-specific antigen (PSA) levels after being treated with local therapy, and slightly more than half of the men were on active surveillance (not yet treated). In the Pomi-T group, median PSA levels rose much less than in the group that took the placebo. The food supplement was well tolerated and
there were no marked differences reported in adverse effects between supplement and placebo groups. However, patients in the supplement group were more likely to have gastrointestinal symptoms (i.e., more gas and loose bowels).

**Lycopene, Selenium, and Green Tea**

A randomized clinical trial of a supplement containing lycopene, selenium, and green tea catechins enrolled men with high-grade prostatic intraepithelial neoplasia (HGPIN). Patients who received the supplement were found to have higher rates of prostate cancer when they had a repeat biopsy after 6 months compared to those who did not receive the supplement. Since this may be due to cancers missed at the start of the study, more research is needed.

**Lycopene and Other Therapies**

A randomized study enrolled 79 patients who were scheduled to undergo prostatectomy. For 3 weeks before the procedure, the men were assigned to consume either: 1) tomato products containing lycopene; 2) tomato products plus selenium, omega 3-fatty acids, soy isoflavones, grape/pomegranate juice, and green/black tea; or 3) a control diet. There were no differences in PSA values between the nutrition-based groups and the control group. However, lower PSA values were found in men with intermediate risk prostate cancer who consumed the tomato products and in patients with the highest increases in lycopene levels.

**Questions and Answers About Zyflamend**

1. **What is Zyflamend?**

   Zyflamend is a dietary supplement that contains extracts of 10 different herbs in olive oil:
   - Rosemary.
   - Turmeric.
   - Ginger.
   - Holy basil.
   - Green tea.
   - Hu zhang (*Polygonum cuspidatum*).
   - Chinese goldthread.
   - Barberry.
   - Oregano.
   - Baikal skullcap.

   The extracts found in Zyflamend have anti-inflammatory activity and possible anticancer benefits. There is limited evidence about how Zyflamend may act against tumor growth. Zyflamend has been shown to interfere with the activity of COX-1 and COX-2 enzymes, which are involved in the development of inflammation and possibly cancer. Zyflamend may also act against the NF-kappa B and lipoxygenase (LOX) families of proteins that stimulate tumor growth.

2. **How is Zyflamend administered or consumed?**

   Zyflamend is taken as a dietary supplement in capsule form.

3. **Have any preclinical (laboratory or animal) studies been conducted using Zyflamend?**

   Laboratory and animal research has recently been done to study the effects of Zyflamend in cancer.

   Studies of Zyflamend in the laboratory have shown the following:
   - Human prostate cancer cells treated with different doses of Zyflamend had lower androgen (male hormone) receptor and prostate-specific antigen (PSA) levels compared with cells treated with a control substance; higher doses of Zyflamend were found to be more effective. Prostate cancer cells treated with
both Zyflamend and bicalutamide (a nonsteroidal antiandrogen drug) showed lower levels of cell growth, PSA, and cancer survival proteins than prostate cancer cells treated with Zyflamend or bicalutamide alone.

- A study in human prostate cancer cells found that a higher concentration of Zyflamend blocked both COX-1 and COX-2 activity; a lower concentration of Zyflamend blocked COX-2 activity but had less effect on COX-1. Zyflamend was also found to limit the growth of prostate cancer cells. However, the prostate cancer cells in the study did not have high levels of COX-2, suggesting that Zyflamend may have effects on prostate cancer cells that are not related to COX activity.

- Prostate cancer cells were treated with insulin-like growth factor-1 (IGF-1, a protein linked with increased risk of prostate cancer) alone or together with Zyflamend. Cells treated with IGF-1 alone grew and spread more, while cells treated with both IGF-1 and Zyflamend grew and spread less. Zyflamend was also shown to decrease levels of the IGF-1 receptor and androgen receptor in prostate cancer cells.

Studies of Zyflamend in animal models of cancer have shown the following:

- Mice implanted with pancreatic tumor cells received either Zyflamend or a control treatment. The mice treated with Zyflamend showed lower levels of cancer survival proteins and higher levels of anticancer activity than mice in the control group.

- Mice implanted with pancreatic tumor cells received either Zyflamend, gemcitabine, or both. Tumor cells from mice that received the combination of Zyflamend and gemcitabine showed a much greater decrease in tumor growth than tumor cells from mice that received Zyflamend or gemcitabine alone. The findings suggested that Zyflamend may have made the pancreatic tumors more sensitive to treatment with gemcitabine.

4. Have any clinical trials (research studies with people) of Zyflamend been conducted?

A report of one patient with high-grade prostatic intraepithelial neoplasia (HGPIN) who received Zyflamend 3 times/day for 18 months showed that PSA levels were not affected. However, at the end of 18 months of treatment, repeat biopsies of the prostate did not show HGPIN or cancer.

In a phase I safety study of Zyflamend, patients with HGPIN took Zyflamend (780 mg) 3 times/day for 18 months with additional dietary supplements (probiotic supplement, multivitamin, green and white tea extract, Baikal skullcap, docosahexaenoic acid, holy basil, and turmeric). Zyflamend and the added dietary supplements were well tolerated and there were no serious side effects. At the end of 18 months of treatment, more than half of patients had benign biopsy results, about one-fourth had HGPIN, and about one in 8 had prostate cancer.

5. Have any side effects or risks been reported from Zyflamend?

A phase I safety study of Zyflamend (described above) reported no toxicity or serious side effects. Some of the patients had mild heartburn that went away when Zyflamend was taken with food.

6. Is Zyflamend approved by the U.S. Food and Drug Administration (FDA) for use as a cancer treatment in the United States?

The U.S. Food and Drug Administration has not approved the use of Zyflamend as a treatment for cancer or any other medical condition.

Zyflamend is available in the United States as a dietary supplement. Dietary supplements are products meant to be added to the diet. They are not drugs and are not meant to treat, prevent, or cure diseases. The manufacturer is responsible for ensuring that the product is safe and that the label claims are truthful and not misleading. The FDA does not approve dietary supplements as safe or effective before they are sold.

Other Prostate Health Supplements

Overview

Many widely available dietary supplements are marketed to support prostate health. African Cherry (*pygeum africanum*) and beta-sitosterol are two related supplements that have been studied as possible prostate cancer...
African Cherry / *P. africanum*

African cherry or *Pygeum africanum* is a tree that grows in tropical climates. It is found in a number of African countries including Kenya, Madagascar, Uganda, and Nigeria. Bark from the *P. africanum* tree was used by African tribes to relieve urinary symptoms and stomach pain. In the 18th century, European travelers learned from South African tribes that *P. africanum* could treat bladder discomfort and “old man’s disease” (enlarged prostate).

Since 1969, bark extracts from *P. africanum* have been available as prescription drugs in Europe and have been widely used to treat benign prostatic hyperplasia (BPH). The bark contains a number of compounds including fatty acids and phytosterols (e.g., beta-sitosterol). The bark is processed and purified as an extract.

Laboratory studies and animal studies have shown that two substances in bark extract from *P. africanum* are active in blocking cells from taking up androgen. The antiandrogen activity found in *P. africanum* is at a markedly lower concentration than the antiandrogen activity found in flutamide (an anticancer drug).

**Beta-Sitosterol**

Beta-sitosterol is a member of the phytosterol family of phytochemicals and is widely found in plant life in different amounts. It is found in African cherry (*Pygeum africanum*), saw palmetto (*Serenoa repens*), and various nuts, beans, and seeds. It is one of several phytosterols (plant sterols) that have a chemical structure similar to cholesterol. Phytosterols, including beta-sitosterol, limit the amount of cholesterol that can be absorbed from the diet and they are being studied for their potential to protect against cardiovascular disease. Beta-sitosterol is very poorly absorbed by the body.

Studies suggest that phytosterols may have anticancer activity, but their exact actions are unknown. Phytosterols may affect immune and hormonal systems or may directly target cell cycles and cause cell death in tumors.

Laboratory studies have shown that high concentrations of beta-sitosterol markedly slow the growth of human prostate cancer cells and cause cancer cell death.

**About This PDQ Summary**

**About PDQ**

Physician Data Query (PDQ) is the National Cancer Institute's (NCI's) comprehensive cancer information database. The PDQ database contains summaries of the latest published information on cancer prevention, detection, genetics, treatment, supportive care, and complementary and alternative medicine. Most summaries come in two versions. The health professional versions have detailed information written in technical language. The patient versions are written in easy-to-understand, nontechnical language. Both versions have cancer information that is accurate and up to date and most versions are also available in Spanish.

PDQ is a service of the NCI. The NCI is part of the National Institutes of Health (NIH). NIH is the federal government’s center of biomedical research. The PDQ summaries are based on an independent review of the medical literature. They are not policy statements of the NCI or the NIH.

**Purpose of This Summary**

This PDQ cancer information summary has current information about the use of nutrition and dietary supplements for reducing the risk of developing prostate cancer or for treating prostate cancer. It is meant to inform and help patients, families, and caregivers. It does not give formal guidelines or recommendations for making decisions about health care.

**Reviewers and Updates**

Editorial Boards write the PDQ cancer information summaries and keep them up to date. These Boards are made up of experts in cancer treatment and other specialties related to cancer. The summaries are reviewed regularly and changes are made when there is new information. The date on each summary ("Date Last Modified") is the date of the most
recent change.

The information in this patient summary was taken from the health professional version, which is reviewed regularly and updated as needed, by the PDQ Integrative, Alternative, and Complementary Therapies Editorial Board.

Clinical Trial Information

A clinical trial is a study to answer a scientific question, such as whether one treatment is better than another. Trials are based on past studies and what has been learned in the laboratory. Each trial answers certain scientific questions in order to find new and better ways to help cancer patients. During treatment clinical trials, information is collected about the effects of a new treatment and how well it works. If a clinical trial shows that a new treatment is better than one currently being used, the new treatment may become "standard." Patients may want to think about taking part in a clinical trial. Some clinical trials are open only to patients who have not started treatment.

Clinical trials are listed in PDQ and can be found online at NCI's website. Many cancer doctors who take part in clinical trials are also listed in PDQ. For more information, call the Cancer Information Service 1-800-4-CANCER (1-800-422-6237).

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Disclaimer

The information in these summaries should not be used to make decisions about insurance reimbursement. More information on insurance coverage is available on Cancer.gov on the Managing Cancer Care page.

Contact Us

More information about contacting us or receiving help with the Cancer.gov website can be found on our Contact Us for Help page. Questions can also be submitted to Cancer.gov through the website’s E-mail Us.

General CAM Information

Complementary and alternative medicine (CAM)—also called integrative medicine—includes a broad range of healing philosophies, approaches, and therapies. A therapy is generally called complementary when it is used in addition to conventional treatments; it is often called alternative when it is used instead of conventional treatment. (Conventional treatments are those that are widely accepted and practiced by the mainstream medical community.) Depending on how they are used, some therapies can be considered either complementary or alternative. Complementary and alternative therapies are used in an effort to prevent illness, reduce stress, prevent or reduce side effects and symptoms, or control or cure disease.

Unlike conventional treatments for cancer, complementary and alternative therapies are often not covered by insurance companies. Patients should check with their insurance provider to find out about coverage for complementary and
alternative therapies.

Cancer patients considering complementary and alternative therapies should discuss this decision with their doctor, nurse, or pharmacist as they would any type of treatment. Some complementary and alternative therapies may affect their standard treatment or may be harmful when used with conventional treatment.

**Evaluation of CAM Therapies**

It is important that the same scientific methods used to test conventional therapies are used to test CAM therapies. The National Cancer Institute and the National Center for Complementary and Integrative Health (NCCIH) are sponsoring a number of clinical trials (research studies) at medical centers to test CAM therapies for use in cancer.

Conventional approaches to cancer treatment have generally been studied for safety and effectiveness through a scientific process that includes clinical trials with large numbers of patients. Less is known about the safety and effectiveness of complementary and alternative methods. Few CAM therapies have been tested using demanding scientific methods. A small number of CAM therapies that were thought to be purely alternative approaches are now being used in cancer treatment—not as cures, but as complementary therapies that may help patients feel better and recover faster. One example is acupuncture. According to a panel of experts at a National Institutes of Health (NIH) meeting in November 1997, acupuncture has been found to help control nausea and vomiting caused by chemotherapy and pain related to surgery. However, some approaches, such as the use of laetrile, have been studied and found not to work and to possibly cause harm.

The NCI Best Case Series Program which was started in 1991, is one way CAM approaches that are being used in practice are being studied. The program is overseen by the NCI’s Office of Cancer Complementary and Alternative Medicine (OCCAM). Health care professionals who offer alternative cancer therapies submit their patients’ medical records and related materials to OCCAM. OCCAM carefully reviews these materials to see if any seem worth further research.

**Questions to Ask Your Health Care Provider About CAM**

When considering complementary and alternative therapies, patients should ask their health care provider the following questions:

- What side effects can be expected?
- What are the risks related to this therapy?
- What benefits can be expected from this therapy?
- Do the known benefits outweigh the risks?
- Will the therapy affect conventional treatment?
- Is this therapy part of a clinical trial?
- If so, who is the sponsor of the trial?
- Will the therapy be covered by health insurance?

**To Learn More About CAM**

*National Center for Complementary and Integrative Health (NCCIH)*

The National Center for Complementary and Integrative Health (NCCIH) at the National Institutes of Health (NIH) facilitates research and evaluation of complementary and alternative practices, and provides information about a variety of approaches to health professionals and the public.

NCCIH Clearinghouse

Post Office Box 7923 Gaithersburg, MD 20898–7923

Telephone: 1-888-644-6226 (toll free)
CAM on PubMed

NCCIH and the NIH National Library of Medicine (NLM) jointly developed CAM on PubMed, a free and easy-to-use search tool for finding CAM-related journal citations. As a subset of the NLM's PubMed bibliographic database, CAM on PubMed features more than 230,000 references and abstracts for CAM-related articles from scientific journals. This database also provides links to the websites of over 1,800 journals, allowing users to view full-text articles. (A subscription or other fee may be required to access full-text articles.)

Office of Cancer Complementary and Alternative Medicine

The NCI Office of Cancer Complementary and Alternative Medicine (OCCAM) coordinates the activities of the NCI in the area of complementary and alternative medicine (CAM). OCCAM supports CAM cancer research and provides information about cancer-related CAM to health providers and the general public via the NCI website.

National Cancer Institute (NCI) Cancer Information Service

U.S. residents may call the NCI Cancer Information Service toll free at 1-800-4-CANCER (1-800-422-6237) Monday through Friday from 8:00 am to 8:00 pm. A trained Cancer Information Specialist is available to answer your questions.

Food and Drug Administration

The Food and Drug Administration (FDA) regulates drugs and medical devices to ensure that they are safe and effective.

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993
Telephone: 1-888-463-6332 (toll free)
Website: http://www.fda.gov

Federal Trade Commission

The Federal Trade Commission (FTC) enforces consumer protection laws. Publications available from the FTC include:

- *Who Cares: Sources of Information About Health Care Products and Services*
- *Fraudulent Health Claims: Don’t Be Fooled*

Consumer Response Center
Federal Trade Commission
600 Pennsylvania Avenue, NW
Washington, DC 20580
Telephone: 1-877-FTC-HELP (1-877-382-4357) (toll free)
TTY (for deaf and hard of hearing callers): 202-326-2502
Website: http://www.ftc.gov

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