Sipuleucel-T immunotherapy for castration-resistant prostate cancer.

Collaborators (84)

Author information

Abstract

BACKGROUND: Sipuleucel-T, an autologous active cellular immunotherapy, has shown evidence of efficacy in reducing the risk of death among men with metastatic castration-resistant prostate cancer.

METHODS: In this double-blind, placebo-controlled, multicenter phase 3 trial, we randomly assigned 512 patients in a 2:1 ratio to receive either sipuleucel-T (341 patients) or placebo (171 patients) administered intravenously every 2 weeks, for a total of three infusions. The primary end point was overall survival, analyzed by means of a stratified Cox regression model adjusted for baseline levels of serum prostate-specific antigen (PSA) and lactate dehydrogenase.

RESULTS: In the sipuleucel-T group, there was a relative reduction of 22% in the risk of death as compared with the placebo group (hazard ratio, 0.78; 95% confidence interval [CI], 0.61 to 0.98; P=0.03). This reduction represented a 4.1-month improvement in median survival (25.8 months in the sipuleucel-T group vs. 21.7 months in the placebo group). The 36-month survival probability was 31.7% in the sipuleucel-T group versus 23.0% in the placebo group. The treatment effect was also observed with the use of an unadjusted Cox model and a log-rank test (hazard ratio, 0.77; 95% CI, 0.61 to 0.97; P=0.02) and after adjustment for use of docetaxel after the study therapy (hazard ratio, 0.78; 95% CI, 0.62 to 0.98; P=0.03). The time to objective disease progression was similar in the two study groups. Immune responses to the immunizing antigen were observed in patients who received sipuleucel-T. Adverse events that were more frequently reported in the sipuleucel-T group than in the placebo group included chills, fever, and headache.

CONCLUSIONS: The use of sipuleucel-T prolonged overall survival among men with metastatic castration-resistant prostate cancer. No effect on the time to disease progression was observed. (Funded by Dendreon; ClinicalTrials.gov number, NCT00065442.)

Comment in

Sipuleucel-T for prostate cancer: the immunotherapy era has commenced. [Expert Rev Anticancer Ther. 2011]
