What this study is about

A study that compared cancer drug treatments after hormone treatment stopped working for men with prostate cancer that spread to other parts of their body (called metastatic).

The official title of this study is: CALGB 90401 (Alliance) A randomized double-blinded placebo controlled phase III trial comparing docetaxel and prednisone with and without bevacizumab (IND #7921, NSC #704865) in men with hormone refractory prostate cancer

Why the study was done

Drugs called docetaxel (Taxotere®) and prednisone are commonly used treatments for prostate cancer for men whose prostate cancer grew after they had hormone therapy. This treatment has helped some patients with prostate cancer live longer if they did not have prior treatment with some other drugs like ketoconazole (Nizoral®). Ketoconazole blocks the way the body makes testosterone. Bevacizumab (Avastin®) is a different kind of treatment (called an antibody) that may help stop the growth of new blood vessels that cancers use.

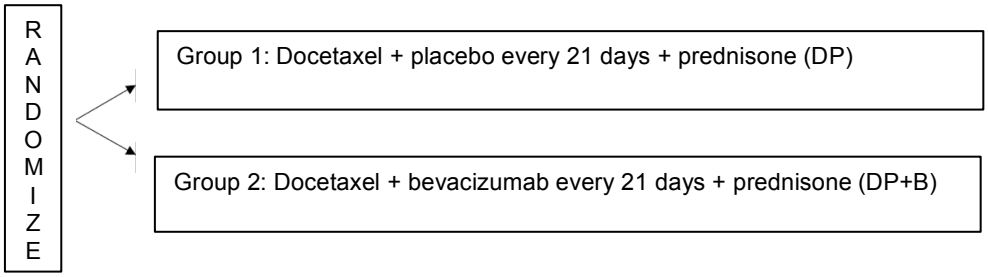
This study was done to see if adding bevacizumab to the common treatment delayed the growth of cancer and allowed patients to live longer. Results (called "outcomes") were compared to see if one group had lower PSA numbers, smaller tumors, more time before a tumor grew again, or lived longer.

This study also measured if men who had prior ketoconazole treatment had a different result on this study than men who did not get it.

How the study worked

Patients were put into two groups by chance (randomized) to reduce differences between the groups. This was done because no one knew if one treatment was better than another.

Here is a picture that explains how patients were placed into one of two groups.



When did the study start and end? The study started in May 2005. All patients were enrolled by December 2007.

How many patients joined? 1005 patients enrolled in this study.

Study results

Important findings:

- Patients in both groups lived almost 2 years after treatment.
- Patients in Group 2 (DP+B) had more time until their tumor grew again (about 10 months) than patients in Group 1 (DP), who had about 8 months.
- About 1 in 2 patients (49.4%) responded to treatment in Group 2 (DP+B), compared to about 1 in 3 patients (35.5%) in Group 1 (DP).
- Patients in Group 2 (DP+B) had more serious side effects than men in Group 1 (DP). More patients in Group 2 died from side effects compared to those in Group 1.
- No risk factors predicted how patients did in either group.
- It did not matter if patients had prior treatment with ketoconazole before starting the treatment in this study.

What the results mean

This study showed that patients in Group 2 had longer cancer-free time, but did not live longer than patients in Group 1. Patients in Group 2 also had worse side effects.

This study also showed that it did not matter if patients took drugs like ketoconazole before starting this treatment.

There was no difference in PSA levels, how much a tumor shrank, how much time until a tumor started to grow again, or how long a patient lived.

These results are for men whose prostate cancer has spread to other parts of their body (metastasized) and whose cancer no longer responds to hormone therapy (called hormone refractory prostate cancer).

Talk to your doctor if you want more information about this study.

Scientific publications about this study

Details about the study can be found in these articles:

- **The effect of prior androgen synthesis inhibition on outcomes of subsequent therapy with docetaxel in patients with metastatic castrate resistant prostate cancer: results from a retrospective analysis of a randomized phase 3 clinical trial (CALGB 90401) (Alliance)**
  Aggarwal R, Halabi S, Kelly WK, et al
  Cancer 2013 [accepted for publication June 3, 2013]
- **Randomized, double-blind, placebo-controlled phase III trial comparing docetaxel and prednisone with or without bevacizumab in men with metastatic castration-resistant prostate cancer: CALGB 90401**
  Kelly WK, Halabi S, Carducci M, et al
  Journal of Clinical Oncology 2012;30:1534-1540

This study was sponsored by the Cancer and Leukemia Group B, which is part of the Alliance for Clinical Trials in Oncology – a national cooperative network that runs large cancer clinical trials. The Alliance is supported by the National Cancer Institute (NCI) and brings researchers together to develop better treatments for cancers. More information about the Alliance is at http://www.allianceforclinicaltrialsinoncology.org.

To learn more about this trial, visit the www.ClinicalTrials.gov website:
http://clinicaltrials.gov/ct2/show/results/NCT00110214?term=90401&rank=1

This summary lists what is known about this research study as of October 2014. New Information may be available.

We thank the people who joined this study and made it possible. *This study could have been completed faster if more people who had the opportunity to participate would have done so. If you know people who are offered the chance to join a cancer clinical trial, please encourage them to enroll. We do research to try to learn the best ways to help patients. The people who joined this study helped us to do that.*

Thank you for your interest in learning more about cancer research advances. We appreciate your advocating for federally-funded research to your elected representatives.