

Frequently asked Questions...

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The Eastern Cooperative Oncology Group (ECOG) prepared this fact sheet to help you understand this cancer clinical trial.

ABOUT E3805 – CHAARTED: CHEMO-HORMONAL THERAPY VERSUS ANDROGEN ABLATION RANDOMIZED TRIAL FOR EXTENSIVE DISEASE IN PROSTATE CANCER

A Clinical Trial for Patients with Prostate Cancer

What is a clinical trial?

A clinical trial is a study conducted by doctors to test new medications or new combinations of medications. This trial – ECOG Trial E3805 – is a “Phase III” trial. That means that the new treatment has already been tested in different doses. Now it needs to be tested to see how it compares to standard treatments.

What is the purpose of this trial?

Standard treatment for extensive prostate cancer is to give hormonal therapy at diagnosis followed by chemotherapy if the cancer gets worse. In this trial, researchers are trying to find out if taking an FDA-approved chemotherapy medication called docetaxel is more effective than the standard treatment when given at diagnosis while also providing this drug, as is standard, if the cancer returns or gets worse.

What are the drugs being used in this trial?

One of the drugs being used in this trial is docetaxel, a chemotherapy medication.

Docetaxel is considered investigational for the treatment of prostate cancer. Other medications used on this trial are called hormonal treatments.

The use of hormonal treatments will be at the discretion of your doctor. Hormonal medications may include “agonists” or “antiandrogens.” Agonists are drugs that cause cells to respond in a certain way. They may include leuprolide, goserelin, or triptorelin. Antiandrogens are drugs that affect the male sex hormones. They may include flutamide and bicalutamide.

What are some of the side effects caused by docetaxel?

The side effects most frequently experienced include nausea, vomiting or diarrhea, increased risk of infection, bruising, or bleeding, fatigue, muscle weakness, and fever. Rare side effects include seizures, blood clots and intestinal damage. Your doctor will discuss all the side effects of docetaxel and standard treatment with you.

What will I have to do on the clinical trial?

If you decide to participate in this trial, your doctor will perform several tests before the trial begins. These include:

- Physical exam
- Blood tests
- Scans of the body (bone scan, chest scan, abdomen/pelvis scan)

You would most likely need to have these tests anyway as part of your routine care for cancer. These tests may be repeated occasionally during the trial. Your doctor or nurse will help you set up a schedule for your tests.

Another part of this study is a Quality of Life Study. It involves completing four questionnaires during the study about how you feel cancer has affected you physically and emotionally during your cancer treatment. Each questionnaire should take approximately 15 minutes to complete. This part of the study is optional and your doctor will explain more about it.

An optional part of the study involves collecting a sample of your blood and a sample of your tumor tissue from your diagnostic biopsy for analysis. With your permission, these samples will be held for future use in research about other health problems.



Will insurance cover the cost of this trial?

Medicare covers the routine costs of care required in clinical trials. Many other insurers also cover these costs. Coverage may not, however, be the same from plan to plan. The cost of the hormonal therapy, doctor's visits, and certain tests may or may not be covered. Please discuss these issues with your healthcare provider and your insurer. The cost of the docetaxel will be free from the manufacturer when receiving hormonal therapy. However, it will not be free if your disease worsens, as this would be standard care.

Is this trial right for me?

To be accepted into this trial, you must have extensive metastatic prostate cancer. If your cancer has spread beyond the pelvic and spinal bones with four or more lesions or involves the liver or lung, you may be eligible for this trial. Men of all ethnic groups are encouraged to participate.

If you would like to participate in this trial, let your doctor know. Your doctor can tell you whether this trial is right for you. If you decide to participate, your doctor will help you understand all the details of the study through a process called "informed consent" before you enroll.

What if I change my mind after enrolling in the trial?

You may stop treatment at any time – please discuss your concerns with your doctor.

Would my doctor stop my participation for any reason?

Your doctor will carefully observe your health throughout the trial. Your doctor may stop your participation if:

- You have serious side effects;
- New information on treating prostate cancer becomes available that may affect your health or welfare.

Who is conducting the trial?

The Eastern Cooperative Oncology Group (ECOG) is conducting this trial. ECOG is one of the largest cancer research organizations in the United States. It has a network of researchers, physicians, and healthcare professionals at public and private institutions across the country. ECOG conducts clinical trials in all types of adult cancers. It receives funding from the National Cancer Institute (NCI) and other sources. ECOG's goal is to control, effectively treat, and ultimately cure cancer. ECOG provides research results to individuals and the medical community through scientific publications and professional meetings.

Where can I get more information?

For more information about ECOG, visit www.ecog.org. For more information about cancer and clinical trials, visit:

The Coalition of Cancer Cooperative Groups:

www.CancerTrialsHelp.org

The National Cancer Institute (NCI) Cancer Information Service: 1-800-4-CANCER (1-800-422-6237) or

TTY: 1-800-332-8615, http://cancer.gov/clinical_trials for clinical trial information and

http://cancer.gov/cancer_information for more information about cancer.

