

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 E2603: A CLINICAL TRIAL FOR PEOPLE WITH STAGE III AND IV INOPERABLE, METASTATIC MELANOMA (SKIN 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 E2603 – is what is called a “phase three” 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 for patients with Stage III and IV melanoma.

A phase three study compares the results of people taking a new treatment with the results of people taking the standard treatment (for example, which group does better or has fewer side effects). In most cases, studies move into phase III only after a treatment seems to work in phases I and II. Phase III trials may include hundreds of people.

What is the purpose of this trial?

The purpose of this study is to compare the effects of carboplatin and paclitaxel (chemotherapy drugs) when given with sorafenib (specialized protein inhibitor also called BAY 43-9006) on you and melanoma cancer.

What should I know about the trial treatments?

Patients will be randomized; meaning assigned by chance like the flip of a coin, to receive carboplatin, paclitaxel, and sorafenib OR carboplatin, paclitaxel, and placebo (a pill that has no active ingredients). Neither you nor your doctor will know if you are taking sorafenib or placebo.

Carboplatin and paclitaxel are FDA approved for use in other types of cancer. They are considered investigational for this study.

Sorafenib is FDA approved for a different type of cancer but is considered investigational in this study.

Will I be getting the optimal therapy for treatment of my stage of disease?

Currently, there are no effective treatments for people with Stages III and IV metastatic melanoma (skin cancer that has spread to other parts of the body) and clinical trials are ongoing to find a treatment. Earlier studies of paclitaxel and carboplatin in much smaller groups of people have shown some effect in slowing the spread of metastatic melanoma. That is why it is important to conduct this trial to study the effects of these medications in 800 people.

What are some of the side effects caused by these medications?

Chemotherapy drugs in general cause side effects including loss of appetite, nausea, vomiting, numbness or tingling in your hands and/or feet, and decreased blood counts with increased risk of infection. There are medications available that can help control the severity of some of these side effects. Some people tolerate side effects better than others. More information on side effects can be found on the National Cancer Institute Web site at <http://www.cancer.gov/cancertopics/chemotherapy-and-you/page4>.

The most frequent side effects reported with the use of sorafenib include rash, tenderness in the hands and feet, diarrhea, and increased blood pressure.

What will I have to do on the clinical trial?

If you decide to participate in this trial, you can expect the following:

- Chemotherapy will be performed in an outpatient setting through an infusion in a vein every three weeks;
- Complete physical exam;
- Blood tests will be performed weekly;
- Scans of the brain and body;
- Pregnancy test, if appropriate



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You would most likely need to have most of these tests and procedures anyway as part of your care for melanoma (skin cancer). Your doctor or nurse will help you set up a schedule for your tests.

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. Please discuss these issues with your physician and your insurer.

Is this trial right for me?

To be accepted into this trial, you must have stage III or IV melanoma (skin cancer) which cannot be surgically removed. Men and women of all ages and ethnic groups can participate.

If you would like to know more about this trial, talk to your doctor. He or she can tell you whether this trial is right for you. If you decide to participate, your doctor will help you enroll.

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

You may leave the trial 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:

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

Who is conducting the trial?

The Eastern Cooperative Oncology Group (ECOG) is coordinating this trial which is being conducted by the NCI-sponsored cooperative groups. 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.



