

Frequently asked Questions...

ABOUT THE THALIDOMIDE NON-SMALL LUNG CANCER (E3598) STUDY

The Eastern Cooperative Oncology Group (ECOG) prepared this fact sheet to help you understand cancer clinical trials and the treatment trial for non-small cell lung cancer with or without thalidomide.

What is a clinical trial?

A clinical trial is a study that helps researchers and doctors find better ways to prevent, treat or diagnose diseases such as cancer. There are several types of cancer clinical trials - some test new ways to treat cancer, others test new methods of prevention, detection or diagnosis. Some clinical trials help evaluate and improve the quality of life for cancer patients.

Trials are conducted in cancer centers, hospitals, clinics, and doctors' offices. Clinical trials answer important scientific questions that can lead to advances in care. All of today's successful treatments for cancer are based on results of clinical trials done in the past. Because of progress made through other clinical trials, people treated for cancer today are living longer.

What is the purpose of this study?

The purpose of this study is to compare the effects (good and bad) of thalidomide when added to the commonly used treatment of carboplatin, paclitaxel and thoracic radiotherapy. The trial will look at you and your lung cancer to see which treatment is better.

Who can participate in this study?

To be eligible for this study, participants must have locally advanced non-small cell lung cancer that cannot be removed by surgery and has not spread. Participants must not have received prior chemotherapy. They must have disease that can be followed. Participants need to be relatively healthy and can perform all activities of daily living. Participants also must have adequate blood, liver and kidney function. They should not have significant heart disease or significant numbness and/or tingling in their hands or feet.

How many people will take part in the study?

About 588 people will take part in the study.

Will I know what drugs I will be taking?

Yes. The study will compare two groups of patients each receiving the commonly used treatment of paclitaxel, carboplatin and thoracic radiotherapy. One group will receive paclitaxel, carboplatin and thoracic radiotherapy. The other group will receive paclitaxel, carboplatin, thoracic radiotherapy and the experimental drug thalidomide.

What is thalidomide?

Thalidomide is a medication, which stops the growth of new blood vessels supplying blood to the tumors. It is hoped a decrease in blood supply to the tumor will "choke it off" and not let oxygen and nutrients get to the tumor. It is also hoped it will prevent the tumor from spreading to other parts of the body.

What is involved in this study?

Patients who participate in this trial will be placed in one of two groups. You will be "randomized" into one of the study groups (Group A or Group B). Randomization means that you are put into a treatment group by chance. It is like the flip of a coin. You and your doctor will not be able to choose which treatment you receive.

Group A: Paclitaxel, Carboplatin and Thoracic Radiotherapy

You will receive chemotherapy with paclitaxel and carboplatin. The paclitaxel will be given to you through a vein and it will take three hours for the drug to be given to you. Immediately after you receive paclitaxel, you will be given carboplatin. It will take 30 minutes to administer carboplatin. You will receive this paclitaxel and carboplatin treatment twice, on day one and again 21 days later.

Three drugs will be given before you receive paclitaxel to control an allergic reaction that may occur.

- A steroid similar to cortisone
- An antacid
- An antihistamine (Benadryl)



After receiving the paclitaxel and carboplatin treatments, you will receive standard radiation therapy to your chest. The radiation therapy is given daily (Monday-Friday) for six weeks. While receiving your radiation therapy you will also receive lower doses of carboplatin and paclitaxel treatments each week.

Group B: Paclitaxel, Carboplatin, Thalidomide and Thoracic Radiotherapy

You will receive chemotherapy with paclitaxel, carboplatin, and thalidomide. The paclitaxel will be given to you through a vein and it will take three hours for the drug to be given to you. Immediately after you receive paclitaxel, you will be given carboplatin. It will take 30 minutes to administer carboplatin. You will receive this paclitaxel and carboplatin treatment twice, on day one and again 21 days later.

Three drugs will be given before you receive paclitaxel to control an allergic reaction that may occur.

- A steroid similar to cortisone
- An antacid
- An antihistamine

You will also start taking thalidomide capsules on day one. You will take thalidomide every day, by mouth, at bedtime. The thalidomide will be taken daily for up to 24 months. Your dose of thalidomide may depend on how well you tolerate the drug.

After receiving the paclitaxel and carboplatin treatments, you will receive standard radiation therapy to your chest. The radiation therapy is given daily (Monday-Friday) for six weeks. While receiving your radiation therapy you will also receive lower doses of carboplatin and paclitaxel treatments each week, as well as your daily thalidomide capsules.

You will have to take some tests during this study. Some of these tests would be done even if you were not participating in the study. These include:

- Physical exam
- Blood tests
- CT scan of chest (a computer takes cross sectional pictures of your body)
- Evaluation of your esophagus (the tube that carries food from your mouth to your stomach). This test will ask how your throat feels, check your weight and monitor the foods you eat.
- EKG (a recording of the electrical activity of your heart)
- Pregnancy tests (for females)
- Central Review: While you are on the study, samples of your tissue, blood, or bone marrow may be sent to a central laboratory to be examined. This review is to confirm the results of the local laboratory review.

What are the benefits to taking part in this study?

If you agree to take part in this study, there may or may not be direct medical benefits to you. We hope the information we learn from this study will help patients who are diagnosed with lung cancer in the future.

However, some possible benefits may include:

- Shrinkage of your tumor
- Prolonged survival

What are the risks?

While on the study, you are at risk for side effects. Be sure to talk with your doctor about all the possible side effects you may experience. You should discuss any side effects you are feeling with your doctor. There may also be other side effects that we cannot predict.

Other drugs will be given to make side effects less serious and less uncomfortable. Most side effects go away shortly after the drugs are stopped, but in some cases side effects can be serious, long lasting or life threatening. This second possibility, however, is much less likely to occur.

Your doctor will check to see if you have any of these side effects. Routine blood tests will be done to look at how well you are receiving the treatment that is given to you.

The side effects for people taking part in the study may include:

Low white blood cell counts (may make you more likely to get a cold), low red blood cell counts (may make you feel tired or weak), low platelet counts (may make you more likely to bruise or bleed), nausea, vomiting, diarrhea, or hair loss. Other uncommon side effects may include: sores in mouth and/or throat, skin rashes, changes in blood pressure, difficulty with breathing, stomach cramps, dizziness, shooting back pain when bending your neck forward, mood changes, or kidney damage.



People on Group B taking thalidomide may experience:

Skin rashes, changes in blood pressure, difficulty with breathing, low white or red blood cell counts, low platelet counts, drop in blood pressure, fatigue, irregular heartbeat, muscle weakness and/or aches or dry skin.

Because the drugs in this study can harm an unborn baby and cause severe birth defects in unborn babies, you should not become pregnant or father a baby while on this study. You should not nurse your baby while on this study.

How long will I be in the study?

You will be in the study for several months. We would like to keep track of your medical condition for five years from the date you start the study.

What if I change my mind and want to stop participating? What are my rights?

Taking part in this study is voluntary. You may change your mind and stop participating at any time. This is your right as a patient. Leaving the study or choosing not to participate will not result in any loss of benefits to which you are entitled nor will it affect your level of care.

However, if you decide to stop participating in the study, we strongly encourage you to talk to your doctor and nurse first.

Also, your doctor may decide to take you off this study if:

- Your cancer gets worse; or
- You have serious side effects to the treatment

Will insurance cover the cost?

Unfortunately, the answer to this question is unclear. Medicare covers the routine costs of care required to participate in clinical treatment trials. Our research shows that many other insurers cover these costs as well. However, coverage may not be consistent from plan to plan.

What other options are there?

If you decide not to take part in this study, you have these options:

- Treatment with different chemotherapy drugs, radiation therapy or both
- Participation on another study
- No therapy at this time

You may receive carboplatin, paclitaxel, and thoracic radiotherapy even if you do not take part in this study. Please talk to your doctor about these and other options.

Where can I get more information before deciding?

You may call the National Cancer Institute Information Service at 1-800-4-CANCER or visit the Web site at <http://cancertrials.nci.nih.gov>

CancerNet also provides accurate information and you can visit it at <http://cancernet.nci.nih.gov>

For more information about the Eastern Cooperative Oncology group (ECOG), visit www.ecog.org.

