

A Phase III Randomized Trial of Lobectomy versus Sublobar Resection for Small (≤ 2 cm) Peripheral Non-Small Cell Lung Cancer

What is a research study or clinical trial?

This is a clinical trial, a type of research study. Your study doctor will explain the clinical trial to you. Clinical trials include only people who choose to take part. Please take your time to make your decision about taking part. You may discuss your decision with your friends and family. You can also discuss it with your health care team. If you have any questions, you can ask your study doctor for more explanation.

You are being asked to take part in this study because you have non-small cell lung cancer which needs to be surgically removed.

Why is this study being done?

The purpose of this study is to test a different way of doing surgery for lung cancer in patients who have small tumors with no evidence of spread. Recent studies have questioned whether removing a larger portion of the lung containing the tumor offers much better control of the cancer than removing a smaller section of the lung. The purpose of this clinical trial is to look at whether removal of a small section of lung (called a sublobar resection) is equal to a lobectomy (a larger surgery which takes out an entire section or 'lobe' of the lung, or about one-quarter to one-half of one lung, depending on which lobe is taken out). This clinical trial will be studying the overall effects (good and/or bad) of a sublobar resection (smaller segment of your lung) compared to a lobectomy (entire lobe of your lung).

How many people will take part in the study?

About 1,400 people will take part in this study.

What will happen if I take part in this research study?

Routine Medical Tests

The following tests and procedure must be done to make sure that you are eligible for this study. None of these tests are research. They are routine. Depending on when you last had them done you may need to repeat some of these tests.

- You will be asked to give your medical history and have a physical examination
- Pulmonary function tests (measures your lungs ability to take air in and out)
- Chest CT scan and x-ray, which can look inside of your chest to measure the tumor
- Your doctor may or may not decide to order a PET scan for you, which can show your doctor where a tumor is at in your body, and if it has spread beyond your lung

Many of these tests will be repeated during the study. If you participate in this study, some of these tests may be done more frequently than if you were not taking part in this study.

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Treatment Plan

If you agree to participate you will be put into one of the two study groups described below. The group you are put into will be chosen by randomization. Randomization means that you are put into a group by chance. During the surgery, your surgeon will examine your tumor and determine if it is the correct size and be sure that the cancer has not spread. Once this is confirmed the research assistant will enter information into a computer program, and the computer program will then randomly place you into one of the study groups while you are still under anesthesia in the operating room. Neither you nor your doctor can choose the group you will be in. You will have an equal chance of being placed in either of the study groups.

If you are in group 1 (often called "Arm A") you will have a standard operation for lung cancer called a lobectomy.

If you are in group 2 (often called "Arm B") you will have a smaller portion of lung removed.

Regardless of the type of surgery done, the entire tumor will be removed. The difference is the amount of surrounding normal lung tissue that is removed with the tumor.

CALGB researchers are interested in reviewing your CT scans and PET scans (if obtained) to see how they relate to your prognosis. Therefore, copies of your scans and reports for the next 3 years will be sent to a CALGB central imaging center for review.

How long will I be in the study?

Before you have surgery on this study you will need to review and sign a separate permission form from your doctor/hospital for the surgery. If, during your operation, it is determined that you are not a candidate for randomization (if your tumor is too large, if it is not the right stage, etc.) then your doctor will decide which operation is right for you and you will no longer take part in this study. Before you have surgery your doctor will discuss what surgery will be done if the tumor does not meet the criteria for this study because of size or stage.

Following your surgery the study doctor will ask you to visit the office for follow-up exams for at least every 3 months for 1 year, then every 6 months for 1 year, and then yearly for up to 5 years. You will need to have a pulmonary function test at 6 months following surgery. Additionally, you will need to have a chest CT at 6 and 12 months after surgery, and then yearly after that for up for 5 years.

Can I stop being in the study?

Yes. You can decide to stop at any time. Tell the study doctor if you are thinking about stopping or decide to stop. He or she will tell you how to stop safely.

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It is important to tell the study doctor if you are thinking about stopping so any risks from the surgery can be evaluated by your doctor. Another reason to tell your doctor that you are thinking about stopping is to discuss what followup care and testing could be most helpful for you.

The study doctor may stop you from taking part in this study at any time if he/she believes it is in your best interest; if you do not follow the study rules; or if the study is stopped.

What side effects or risks can I expect from being in the study?

You may have side effects while on the study. Everyone taking part in the study will be watched carefully for any side effects. However, doctors don't know all the side effects that may happen. Side effects may be mild or very serious. Some side effects may be unexpected or unforeseen. Your health care team may give you medicines to help lessen side effects.

Both lobectomy and sublobar resection have risks associated with them. We believe that the risks may be less after sublobar resection, but it is possible they could be the same or even greater. There is a risk that sublobar resection will not be as effective at removing the cancer, which could possibly lead to a higher risk of the cancer returning. If the cancer returns, it may be less curable at that time.

You should talk to your study doctor about any side effects that you have while taking part in the study.

The risks of surgery include:

Likely:

- Air leaking from the part of the lung that was operated on

Less Likely:

- Pneumonia

Rare:

- Infection in the area around the lung, wound infection or blood infection
- Bleeding
- Poor healing of the skin and/or muscles in the chest

For more information about risks and side effects, ask your study doctor.

Will I benefit from taking part in the study?

Taking part in this study may or may not make your health better. While doctors hope a smaller resection will be as good as the usual treatment, this has not yet been proven. The reason for this study is to investigate this possibility. We do know that the information from this study will help doctors learn more about a sublobar resection when

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compared to a lobectomy, as a treatment for cancer. This information could help future cancer patients.

What other choices do I have if I do not take part in this study?

Your other choices may include:

- Getting treatment or care for your cancer without being in this study (examples include having surgery without being on this study, or getting treatment other than surgery, like radiation or chemotherapy)

Talk to your doctor about your choices before you decide if you will take part in this study.

Will my medical information be kept private?

We will do our best to make sure that the personal information in your medical record will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

A record of your progress will be kept in a confidential form at your hospital or doctor's office where you receive treatment. Organizations that may inspect and/or copy your research and medical records (blood samples, x-rays, scans, pathology slides, etc.) for quality assurance, research, and data analysis include groups such as:

- Southeast Cancer Control Consortium (SCCC) Operations Office
- Cancer and Leukemia Group B (CALGB)
- CALGB Imaging Core Laboratory
- National Cancer Institute (NCI) and its representatives
- Food and Drug Administration (FDA)
- Office for Human Research Protections (OHRP)
- Institutional Review Board (IRB) at _____ Hospital
- Possible other federal or state government agencies

If your record is used or given out for governmental purposes, it will be done under conditions that will protect your privacy to the fullest extent possible consistent with laws relating to public disclosure of information and law-enforcement responsibilities of the agency. These agencies may review the research to see that it is being done safely and correctly.

You authorize the use of clinical information contained in your records, but any publication which includes such information or data shall not reveal your name, show your picture or contain any other personally identifying information, except as otherwise required by law.

What are the costs of taking part in this study?

You and/or your health plan/insurance provider (Medicare should be considered a health insurance provider) will need to pay for some or all of the costs of treating your cancer in this study. Some health plans will not pay these costs for people taking part in studies. Check with your health plan or insurance company to find out what they will pay for. Taking part in this study may or may not cost your insurance company more than the cost of getting regular cancer treatment. You or your insurance carrier will be responsible for the costs of clinic visits, any hospital admissions, laboratory tests, x-rays, scans, chemotherapy treatments, radiation treatments, and any other tests. You will not be charged for the shipment of the x-rays and scans to the CALGB central imaging center. Please ask your doctor about any added costs or insurance problems.

For more information on clinical trials and insurance coverage, you can visit the National Cancer Institute's Web site at <http://cancer.gov/clinicaltrials/understanding/insurance-coverage>. You can print a copy of the "Clinical Trials and Insurance Coverage" information from this Web site.

You will not be paid to participate in this study.

What happens if I am injured because I took part in this study?

It is important that you tell your study doctor, _____ if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or call him/her at # _____.

You will get medical treatment if you are injured as a result of taking part in this study. You and/or your health plan will be charged for this treatment. The study will not pay for medical treatment. Although no funds or monies have been set aside to compensate you in the event of injury or illness related to the study treatment or procedures, you do not waive any of your legal rights for compensation by signing this form.

You or your insurance company will be charged for continuing medical care and/or hospitalization.

What are my rights if I take part in this study?

Taking part in this study is voluntary. You may choose to take part, not to take part, or may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care or result in any penalty or loss of benefits to which you are entitled.

Even after you agree to take part in this study, you may withdraw at any time. Before you withdraw, you should talk to one of the researchers or nurses involved. This will allow them to inform you of any medical problems that could result from stopping your treatment. You can choose to withdraw one of two ways. In the first, you can stop your study treatment, but still allow the study doctor to follow your care. In the second, you

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can stop your study treatment and not have any further contact with the study staff. Either way, there will be no penalty to you. Your decision will not affect your medical treatment or your relationship with those treating you or with this institution. If you withdraw from the study, you will still be offered all available care that suits your needs and medical condition. You are free to seek care from a doctor of your choice at any time.

A Data Safety and Monitoring Committee (DSMC), an independent group of experts, will be reviewing the data from this research throughout the study. The DSMC is a committee assigned to a randomized clinical trial charged or obligated with the responsibility of monitoring performance of the trial, safety of the participants, and effectiveness of the treatments being tested.

We will tell you about new information that may affect your health, welfare or willingness to stay in this study. You may be asked to sign another consent form in response to new information.

Who can answer my questions about the study?

For questions about the study or a research-related injury, contact your doctor, _____, at # _____. You may ask your doctor for further information on the risks, benefits or alternative treatments.

For questions about your rights as a research participant, contact the _____ Institutional Review Board (which is a group of people at the hospital in the community where you receive treatment who review the research to protect your rights) at # _____ (the office of _____).

Where can I get more information?

- You may call the National Cancer Institute's (NCI's) Cancer Information Service at:
1-800-4-CANCER (1-800-422-6237) or TTY: 1-800-332-8615
- You may also visit the NCI Web site at <http://cancer.gov>
- For the NCI's clinical trials information, go to: <http://cancer.gov/clinicaltrials>
- For the NCI's general information about cancer, go to:
<http://cancer.gov/cancerinfo>

Participant Agreement

I have been offered the opportunity to ask questions about this study and all questions have been answered to my satisfaction. The contents of this form have been explained to me and I understand them. I agree to allow the research personnel specified above the access to my medical records.

It may be necessary for my doctor to contact me at a future date regarding new information about the treatment I received; therefore I agree to notify my doctor of any change of address and/or telephone number.

My signature below means that I have voluntarily agreed to participate in this research study. I will be given a copy of all 7 pages of this consent. I have read it or it has been read to me. I may also request a copy of the study (complete study plan).

(Date)

(Participant Signature)

I certify that I have explained to the above individual the nature and purpose, the potential benefits, and possible risks associated with participation in the research study and have answered any questions that have been raised.

(Date)

(Signature of Person Obtaining Consent)