Study Title for Study Participants:

Testing whether or not a drug that is known to "target" a certain kind of lung tumor works in patients with that type of tumor

Official Study Title for Internet Search on http://www.ClinicalTrials.gov:

Randomized Study of Erlotinib or Observation in Patients with Completely Resected Epidermal Growth Factor Receptor (EGFR) Mutant Non-small Cell Lung Cancer (NSCLC)

What is the usual approach to my lung cancer?

The standard treatment for your type of lung cancer is chemotherapy and sometimes radiation therapy.

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

If you decide not to take part in this study, you have other choices. For example:

- You may choose to have the usual approach described above
- You may choose to take part in a different study, if one is available
- Or you may choose not to be treated for cancer but you may want to receive comfort care to relieve symptoms.

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

Why is this study being done?

The purpose of this study is to compare any good and bad effects patients may have when treated with the standard treatment against patients who are treated with the standard treatment plus erlotinib (an investigational drug). You are being asked to take part in this research study because you have early stage non-small cell lung cancer that was surgically removed and may have been treated with chemotherapy and/or radiation. The tumor removed has a mutation of a gene called EGFR (Epidermal Growth Factor Receptor). We are trying to find out if this mutation could help us make decisions about which type of treatment is best for people with your type of cancer. People not in a research study are usually not treated with anything after they finish their chemotherapy although some of them may receive radiation therapy.

A total of 450 patients will participate in this trial.

What are the study groups?
This study has two study groups.

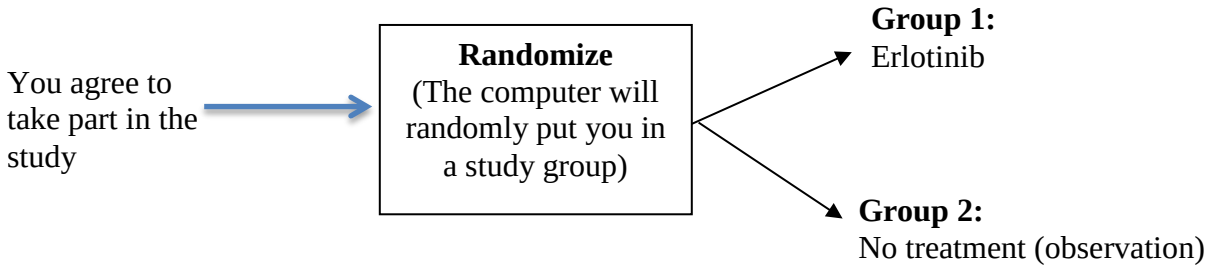
- Group 1 will get the study drug called erlotinib. The erlotinib will be taken once a day.
- Group 2 will not receive the erlotinib and will be followed by their doctor.

Group 1: Treatment with erlotinib will last for up to 2 years, as long as you do not have too many side-effects and the tumor has not grown back. While you are receiving treatment you will see your doctor for a check-up and certain tests every 3 weeks for the first 6 weeks after you start treatment (at weeks 3 and 6), then every 6 weeks for 12 weeks (at weeks 12 and 18), and then at least every 12 weeks while you continue on treatment.

Group 2: Patients not receiving the erlotinib will see their doctor every 6 months for 4 years. After 4 years you will be seen every year for an additional 6 years, as long as the cancer does not return.

You will be "randomized" into one of the study groups described above. Randomization means that you are put into a group by chance. A computer program will place you in one of the study groups. This is done because no one knows if one study group is better, the same, or worse than the other. Once you are put into 1 group you cannot switch to another group. Neither you nor your study doctor can choose the group you will be in. You will have an equal chance of being placed in either group.

By the time enrollment to the study is finished, there will be a roughly equal number of people in each group.
Another way to find out what will happen to you during this study is to read the chart below. Start reading at the left side and read across to the right, following the arrows.



The erlotinib should not be taken with grapefruit or grapefruit juice. Erlotinib should be taken 1 hour before or 2 hours after a meal.

How long will I be in the study?

Patients randomized to erlotinib will have treatment with erlotinib for up to 2 years, or until the tumor grows or you have bad side-effects. You will then see your study doctor every 6

months for the first 4 years after starting treatment, and then yearly for the following 6 years, for a total of 10 years. You will also have a CT scan during these visits.

Patients randomized to observation will see their study doctor every 6 months for 4 years, then yearly for another 6 years. You will also have a CT scan during these visits.

There may come a time when your study doctor may decide to take you off study even though you want to continue to participate. This may happen if:

- You are unable to meet the ongoing requirements of the study;
- Your medical condition changes and it is no longer appropriate for you to participate;
- If it is determined the study must stop.

You can stop participating at any time. However, if you decide to stop participating in the study, we encourage you to talk to your study doctor first.

What risks can I expect from taking part in this study?

If you choose to take part in this study, there is a risk that you may lose time at work or home and spend more time in the hospital or doctor's office than usual

The laboratory test that found the EGFR gene mutation in your tumor is investigational, but it is similar to other FDA approved tests. The EGFR testing to help guide treatment is well established, however, there is a slight risk that, since the investigational test is being used to determine treatment, the treatment you receive may not be the best treatment for you. One of the reasons we are doing this study is to find the best treatment for patients like you.

The study drugs used in this study may affect how different parts of your body work such as your liver, kidneys, heart, and blood. The study doctor will be testing your blood and will let you know if changes occur that may affect your health.

There is also a risk that you could have side effects.

Here are important points about side effects:

- The study doctors do not know who will or will not have side effects.
- Some side effects may go away soon, some may last a long time, or some may never go away.
- Some side effects may interfere with your ability to have children.
- Some side effects may be serious and may even result in death.

Here are important points about how you and the study doctor can make side effects less of a problem:

- Tell the study doctor if you notice or feel anything different so they can see if you are having a side effect.
- The study doctor may be able to treat some side effects.
- The study doctor may adjust the study drugs to try to reduce side effects.

The tables below show the most common and the most serious side effects that researchers know about. There might be other side effects that researchers do not yet know about. If important new side effects are found, the study doctor will discuss these with you.

Possible side-effects of erlotinib

COMMON, SOME MAY BE SERIOUS In 100 people receiving erlotinib, more than 20 and up to 100 may have:
• Diarrhea • Rash

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving erlotinib, from 4 to 20 may have:
• Dry eye, mouth, skin • Changes in eyelashes, taste • Belly pain • Heartburn, nausea, vomiting • Bleeding from multiple sites including the nose • Internal bleeding which may cause black tarry stool, blood in vomit • Sores in the mouth which may cause difficulty swallowing • Infection • Dehydration • Headache • Cough, shortness of breath • Damage to the lungs which may cause shortness of breath • Hair loss, itching, acne • Loss of some or all of the nails • Tiredness • Loss of appetite

RARE, AND SERIOUS In 100 people receiving erlotinib, 3 or fewer may have:
• Blood clot which may cause bleeding, confusion, paralysis, seizures and blindness • Anemia, kidney problems which may cause tiredness, bruising, swelling, or may require dialysis • Heart attack • A tear or hole in internal organs that may require surgery which may cause blurred vision • Swelling and redness of the eye

- Liver damage which may cause yellowing of eyes and skin, swelling
- Bleeding in the brain
- Stroke which may cause weakness
- Kidney damage which may require dialysis
- Redness, pain or peeling of palms and soles
- Severe skin rash with blisters and peeling which can involve mouth and other parts of the body
- Sores in the eye
- Blister on the skin

Reproductive risks: You should not get pregnant, breastfeed, or father a baby while in this study. The treatment used in this study could be very damaging to an unborn baby. Women of childbearing potential must use effective contraception during treatment and for one month after the last dose of erlotinib. Check with the study doctor about what types of birth control, or pregnancy prevention, to use while in this study.

Will I benefit from this study?

This study may or may not help you. We hope the study will help us determine what treatment is most effective in treating lung cancer. We hope the information learned from this study will benefit other patients with lung cancer in the future.

Can I stop being in the study?

Yes. You can decide to stop at any time. If you decide to stop for any reason, it is important to let the study doctor know as soon as possible so you can stop safely. If you stop you can decide whether or not to let the study doctor continue to provide your medical information to the Alliance (the organization running the study).
The study doctor will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

The study doctor may take you out of the study:

- If your health changes and the study is no longer in your best interest;
- If new information becomes available
- If you do not follow the study rules
- If the study is stopped by the sponsor

What are my rights as a participant?

Taking part in this study is your choice. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

For questions about your rights while in this study, you may contact the Operations Office of the National Cancer Institute (NCI) Central Institutional Review Board (CIRB) at 888-657-3711.

What are the costs?

The erlotinib will be supplied at no charge while you take part in this study. The cost of getting the erlotinib ready and giving it to you is a separate charge, and you or your insurance company may have to pay for this. It is possible that the erlotinib may not continue to be supplied while you are on the study. Although not likely, if this occurs, your study doctor will talk to you about your options.

You and/or your health plan/ insurance company will need to pay for all of the other costs of treating your cancer while in this study, including the cost of tests, procedures, or medicines to manage any side effects, unless you are told that certain tests are supplied at no charge. Before you decide to be in the study, you should check with your health plan or insurance company to find out exactly what they will pay for.

You will not be paid for taking part in this study.

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

If you are injured or hurt as a result of taking part in this study and need medical treatment, please tell your study doctor. Contact information for your study doctor is listed on the consent cover page. The study sponsors will not offer to pay for medical treatment for injury. Your insurance company may not be willing to pay for study-related injury. If you have no insurance, you would be responsible for any costs.

If you feel this injury was a result of medical error, you keep all your legal rights to receive payment for this even though you are in a study.

No funds have been set aside to compensate you in the event of injury.

Who will see my medical information?

Your privacy is very important to us and the researchers will make every effort to protect it. Your information may be given out if required by law. For example, certain states require doctors to report to health boards if they find a disease like tuberculosis. However, the researchers will do their best to make sure that any information that is released will not identify you. Some of your health information, and/or information about your specimen, from this study will be kept in a central database for research. Your name or contact information will not be put in the database.
There are organizations that may inspect your records. These organizations are required to make sure your information is kept private, unless required by law to provide information. Some of these organizations are:

- Montana Cancer Consortium
- The study sponsor and any drug company supporting the study.
- Astellas, Inc. or future collaborator, the manufacturer of erlotinib.

- The Institutional Review Board, IRB, is a group of people who review the research with the goal of protecting the people who take part in the study.
- The Food and Drug Administration and the National Cancer Institute in the U.S., and similar ones if other countries are involved in the study.

Where can I get more information?

You may visit the NCI Web site at http://cancer.gov/ for more information about studies or general information about cancer. You may also call the NCI Cancer Information Service to get the same information at: 1-800-4-CANCER (1-800-422-6237).

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Who can answer questions about this study?

You can talk to the study doctor about any questions or concerns you have about this study or to report side effects or injuries. Contact information for your study doctor is listed on the consent cover page.

ADDITIONAL STUDIES SECTION:

This section is about optional studies you can choose to take part in.

This part of the consent form is about optional studies that you can choose to take part in. You will not get health benefits from any of these studies. The researchers leading this optional study hope the results will help other people with cancer in the future.

The results will not be added to your medical records and you or your study doctor will not know the results.

You will not be billed for these optional studies. You can still take part in the main study even if you say “no” to any or all of these studies. If you sign up for but cannot complete any of the studies for any reason, you can still take part in the main study.

Circle your choice of “yes” or “no” for each of the following studies.

Optional Sample Collections for Laboratory Studies and/or Biobanking for Possible Future Studies

Researchers are trying to learn more about lung cancer. Some of this research is done using samples of blood. Through these studies, researchers hope to find new ways to prevent, detect, treat, or cure lung cancer.

Some of these studies may be about genes. Genes carry information about features that are found in you and in people who are related to you. Genes also carry information about your cancer. Researchers are interested in the way that genes affect how your body responds to treatment.

If you choose to take part in this study, the study doctor for the main study would like to collect blood for research on whether genetic information (or "DNA") from your cancer can be detected in your blood. This type of blood test, or "liquid biopsy" aims to be able to personalize cancer treatment by looking for characteristics of a cancer within a patient's blood. If cancer DNA can be detected in your blood, then this may allow researchers to better plan treatment for your lung cancer. The results from this blood test would be investigational and would not be returned to your treating physician.

If you choose to take part, blood will be collected. The researchers ask your permission to store and use your samples and related health information (for example, your response to cancer treatment, results of study tests and medicines you are given) for medical research. Some of the research that may be done is unknown at this time. Storing samples for future studies is called "biobanking". The Biobank is being run by the National Cancer Institute.

WHAT IS INVOLVED?

If you agree to take part, here is what will happen next:

1) About 1½ tablespoons of blood will be collected from a vein in your arm prior to treatment, then every 6 months for 4 years, and then every year for another 6 years.
2) Your sample and some related health information will be sent to a researcher for use in the study described above. Remaining samples may be stored in the Biobank, along with samples from other people who take part. The samples will be kept until they are used up.
3) Qualified researchers can submit a request to use the materials stored in the Biobanks. A science committee at the clinical trials organization, and/or the National Cancer Institute, will review each request. There will also be an ethics review to ensure that the request is necessary and proper. Researchers will not be given your name or any other information that could directly identify you.

4) Neither you nor your study doctor will be notified when research will be conducted or given reports or other information about any research that is done using your samples.
5) Some of your genetic and health information may be placed in central databases that may be public, along with information from many other people. Information that could directly identify you will not be included.
6) Your specimens will be labeled with your initials and the dates that they were taken. The will be sent to the lab at the National Cancer Institute.

WHAT ARE THE POSSIBLE RISKS?

1) The most common risks related to drawing blood from your arm are brief pain and possibly a bruise.
2) There is a risk that someone could get access to the personal information in your medical records or other information researchers have stored about you.
3) There is a risk that someone could trace the information in a central database back to you. Even without your name or other identifiers, your genetic information is unique to you. The researchers believe the chance that someone will identify you is very small, but the risk may change in the future as people come up with new ways of tracing information.
4) In some cases, this information could be used to make it harder for you to get or keep a job or insurance. There are laws against the misuse of genetic information, but they may not give full protection. There can also be a risk in knowing genetic information. New health information about inherited traits that might affect you or your blood relatives could be found during a study. The researchers believe the chance these things will happen is very small, but cannot promise that they will not occur.

HOW WILL INFORMATION ABOUT ME BE KEPT PRIVATE?

Your privacy is very important to the researchers and they will make every effort to protect it. Here are just a few of the steps they will take:

1) When your sample is sent to the researchers, no information identifying you (such as your name) will be sent. Samples will be identified by a unique code only.
2) The list that links the unique code to your name will be kept separate from your sample and health information. Any Biobank and the Alliance staff with access to the list must sign an agreement to keep your identity confidential.
3) Researchers to whom the Alliance sends your sample and information will not know who you are. They must also sign an agreement that they will not try to find out who you are.
4) Information that identifies you will not be given to anyone, unless required by law.
5) If research results are published, your name and other personal information will not be used.

WHAT ARE THE POSSIBLE BENEFITS?

You will not benefit from taking part. The researchers, using the samples from you and others, might make discoveries that could help people in the future.

ARE THERE ANY COSTS OR PAYMENTS?

There are no costs to you or your insurance. You will not be paid for taking part. If any of the research leads to new tests, drugs, or other commercial products, you will not share in any profits.

WHAT IF I CHANGE MY MIND?

If you decide you no longer want your samples to be used, you can call the study doctor, who will let the researchers know. Contact information for your study doctor is listed on the consent cover page. Then, any sample that remains in the bank will no longer be used and related health information will no longer be collected. Samples or related information that have already been given to or used by researchers will not be returned.

WHAT IF I HAVE MORE QUESTIONS?

If you have questions about the use of your samples for research, contact the study doctor. Contact information for your study doctor is listed on the consent cover page.

Please circle your answer to show whether or not you would like to take part in each option (*include only applicable questions)*:

SAMPLES FOR THE LABORATORY STUDIES:

I agree to have my blood collected and I agree that my blood samples and related information may be used for the laboratory study described above.

YES NO

SAMPLES FOR FUTURE RESEARCH STUDIES:

My blood samples and related information may be kept in a Biobank for use in future health research.

YES NO

I agree that my study doctor, or their representative, may contact me or my physician to see if I wish to participate in other research in the future.

YES NO

This is the end of the section about optional studies.

Signature:

This study has been explained to me, and I have been told what my enrollment in the study involves. I have read all pages of this consent and have had my questions answered to my satisfaction at this time. I consent to participate in this study and any additional studies where I circled 'yes'. I understand that by signing this form I have not given up any of my legal rights. I will be given a copy of this consent form. I may also request a copy of the protocol (full study plan).

Participant Signature: _____

Date: _____

Signature of Person Obtaining Consent: _____

Date: _____

Time of consent: _____ (AM) (PM)
(Required for initial consent only)