



ALCHEMIST*

ERLOTINIB TREATMENT TRIAL (A081105)

WHY YOU ARE IMPORTANT TO OUR STUDY

Thank you for participating in the ALCHEMIST screening trial. Your laboratory results show that you are among the ten percent of patients whose tumors have the EGFR mutation.

This means that you are now in a small group who has the opportunity to join the ALCHEMIST treatment trial that will use erlotinib, a newly developed medicine specifically made to attack cancer by targeting EGFR. Because relatively few patients have tumors with EGFR mutations, it is vital to the success of this trial for as many eligible patients as possible to enroll. Your participation is very important to us.

WHY OUR STUDY IS IMPORTANT TO YOU AND PATIENTS LIKE YOU

ALCHEMIST includes several clinical trials. Their goal is to test new therapies for patients like you: those with early stage non-small cell lung cancer whose tumor has been surgically removed. These new therapies may represent a significant advance in the treatment of your cancer.

Erlotinib has proven to be effective for patients with more advanced stages of non-small cell lung cancer, and is FDA approved for those patients. This ALCHEMIST treatment trial is testing if erlotinib also helps patients like you whose cancer is not as advanced. The trial will allow researchers to know whether adding this drug after usual treatment is better than, the same as, or inferior to the usual treatment for your type of cancer. Erlotinib is still investigational (not approved by the FDA) for early stage lung cancer.

WOULD THIS REPLACE MY USUAL TREATMENT?

No. You will complete the treatment plan that you and your doctor decided on and then you will begin the erlotinib trial. Being in the erlotinib trial does not replace or eliminate any treatment that doctors would usually recommend.

HOW DOES THE ALCHEMIST ERLOTINIB TREATMENT TRIAL WORK?

A computer will place you randomly (by chance) into one of two groups. One group will receive erlotinib, the drug being tested in this trial. The other group will be observed and followed by their doctor at check-ups every 6 months. You will have an equal chance of being in either group.

WHY WILL SOME PATIENTS NOT RECEIVE ERLOTINIB?

We will compare the outcome of patients in the erlotinib group to those in the observation group to try to see which is better: adding erlotinib or not after the usual treatment. It also could turn out that there is no difference or that adding erlotinib is worse for a patient. Patients who do not receive erlotinib will be observed and followed by their doctor (similar to patients who do not go on this trial).

HOW LONG WILL I BE IN THE TRIAL?

Patients in the treatment group will receive erlotinib for two years. During this time you will be required to see your doctor and have certain tests at specified intervals. After the erlotinib treatment is finished, you will see your doctor every six months for four years, and then every year for six years – a total of 10 years.

If you decide not to be in the treatment trial, we will continue to monitor you and all the patients who entered the screening trial. One of our doctors will contact you every six months for five years. You may leave the treatment trial at any time if you change your mind.

WILL I HAVE TO PAY TO BE IN THE TRIAL?

Erlotinib is provided at no cost to you. Your health insurance and you may be responsible for some other costs. A trial representative will discuss these costs with you. You should check with your health plan or insurance company to find out exactly what they will pay for before you decide to be in the trial.

ARE THERE RISKS TO BEING IN THE TRIAL?

All of the possible risks are clearly stated in the trial consent form, which you must carefully review and sign before participating.

TELL ME AGAIN WHY MY PARTICIPATION IS IMPORTANT?

For patients with early stage non-small cell lung cancer, there is a 50 percent chance that the cancer will come back, even after they receive the usual treatment (surgery, chemotherapy and/or radiation). The ALCHEMIST trial is testing to see if adding extra treatment – after the usual treatment – will improve the odds that the cancer will not return. Targeted therapies like erlotinib may be able to slow or stop cancer in more ways than older treatments. As part of ALCHEMIST, you can help us test these therapies, for you and for future cancer patients.

WHAT SHOULD I DO IF I'M INTERESTED?

Ask for the ALCHEMIST erlotinib treatment trial consent form and review it with your doctor. You can also find out more at: www.cancer.gov/alchemist

Thank you for your interest in the ALCHEMIST erlotinib treatment trial.

