



ALCHEMIST*

CRIZOTINIB TREATMENT TRIAL (E4512)

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 five percent of patients whose tumor cells have a change in a gene called ALK that causes the cells to grow and spread.

This means that you are now in a small group who has the opportunity to join the ALCHEMIST treatment trial that will use crizotinib, a newly developed medicine specifically made to attack cancer by targeting ALK. Because relatively few patients have tumors with ALK changes, 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.

Crizotinib has proven to be effective for patients with more advanced stages of non-small cell lung cancer with ALK gene changes, and is FDA approved for those patients. This ALCHEMIST treatment trial is testing crizotinib in 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 worse than the usual treatment for your type of 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 crizotinib trial. Being in the crizotinib trial does not replace or eliminate any treatment that doctors would usually recommend.

HOW DOES THE ALCHEMIST CRIZOTINIB TREATMENT TRIAL WORK?

A computer will place you randomly (by chance) into one of two groups. One group will receive crizotinib, and the other will receive a placebo. The placebo looks like the drug being tested, but does not contain any active drug. Both the crizotinib and the placebo are given as pills that you swallow.

WHY WILL SOME PATIENTS NOT RECEIVE CRIZOTINIB?

We will compare the outcome of patients in the crizotinib group to those in the placebo group to try to see which is better: adding crizotinib or not after the usual treatment. It also could turn out that there is no difference or that adding crizotinib is worse for a patient. Patients who receive the placebo have already had the usual treatment for their kind of cancer (because everyone will have had usual treatment before starting the crizotinib treatment trial).

This is why you will be assigned to a group by chance. You will have an equal chance of being in either group, and neither you nor your doctor will know which group you are in.

HOW LONG WILL I BE IN THE TRIAL?

You will receive treatment for up to two years. During this time you will be required to see your regular doctor and have certain tests at specified intervals. Once the trial begins, you will see your study 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?

The crizotinib and placebo are 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 crizotinib 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 crizotinib 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 crizotinib treatment trial.

