



ALCHEMIST*

NIVOLUMAB TREATMENT TRIAL (EA5142)

WHY YOU ARE IMPORTANT TO OUR STUDY

Thank you for participating in the ALCHEMIST screening trial. Your laboratory results show that you may potentially be eligible to take part in the newest of the ALCHEMIST treatment trials: the nivolumab treatment trial.

This treatment trial was created for patients with squamous non-small cell lung cancer, or, for patients with non-squamous, non-small cell lung cancer whose tumors do not contain the ALK or EGFR gene changes. As a patient in either of these groups, you may have the opportunity to receive nivolumab, a type of medicine called “immunotherapy,” which may help your own immune system prevent the cancer from returning. Nivolumab works by blocking a protein (called PD-L1) in the tumor that stops the immune system from attacking the cancer cells.

WHY OUR STUDY IS IMPORTANT TO YOU AND PATIENTS LIKE YOU

Nivolumab has proven to be effective for patients with more advanced stages of non-small cell lung cancer who had chemotherapy, and is FDA approved for those patients. This ALCHEMIST treatment trial is testing nivolumab 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 nivolumab trial. Being in the nivolumab trial does not replace or eliminate any treatment that doctors would usually recommend.

HOW DOES THE ALCHEMIST NIVOLUMAB TREATMENT TRIAL WORK?

A computer will place you randomly (by chance) into one of two groups. One group will receive nivolumab, and the other will be observed in the same way that patients who are not in the trial would be.

WHY WILL SOME PATIENTS NOT RECEIVE NIVOLUMAB?

We will compare the outcome of patients in the nivolumab group to those in the observation group to see which is better: adding nivolumab or not after the usual treatment. It also could turn out that there is no difference or that adding nivolumab is worse for a patient. Patients in the observation group have already had the usual treatment for their kind of cancer (because everyone will have had usual treatment before starting the nivolumab 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 both you and your doctor will be informed of which group you are in.

HOW LONG WILL I BE IN THE TRIAL?

You will receive treatment for one year. 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 after they are screened. 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 nivolumab is provided at no cost to you. Your health insurance or 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 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. Nivolumab has proven to be effective for people with more advanced forms of lung cancer. ALCHEMIST is the first trial to study nivolumab for patients who have early stage non-small cell lung cancer. As part of the study, you can help us test this treatment, for you and for future cancer patients.

WHAT SHOULD I DO IF I'M INTERESTED?

Ask for the ALCHEMIST nivolumab 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 nivolumab treatment trial.

