ForPatients
by Roche

Non-Small Cell Lung Cancer (NSCLC) Non Small Cell Lung Carcinoma

A Clinical Trial to Compare Alectinib Versus Chemotherapy After Surgery in Patients with ALK-Positive Non-Small Cell Lung Cancer (ALINA)

A Phase III, Open-Label, Randomized Study to Evaluate the Efficacy and Safety of Adjuvant Alectinib Versus Adjuvant Platinum-Based Chemotherapy in Patients With Completely Resected Stage IB (Tumors Equal to or Larger Than 4cm) to Stage IIIA Anaplastic Lymphoma Kinase Positive Non-Small Cell Lung Cancer

Trial Status	Trial Runs In	Trial Identifier
Active, not recruiting	27 Countries	NCT03456076 2017-004331-37 BO40336

The source of the below information is the publicly available website ClinicalTrials.gov. It has been summarised and edited into simpler language.

Trial Summary:

This randomized, active-controlled, multicenter, open-label, Phase III study is designed to investigate the efficacy and safety of alectinib compared with platinum-based in the adjuvant setting. Participants in the experimental arm will receive alectinib at 600 mg orally twice daily (BID) taken with food for 24 months. Participants in the control arm will receive one of the protocol specified platinum based chemotherapy regimens for 4 cycles. Following treatment completion, participants will be followed up for their disease until disease recurrence. At the time of disease recurrence, participants will enter a survival follow-up until death, withdrawal of consent or study closure, whichever occurs earlier.

Hoffmann-La Roche	Phase 3
Sponsor	Phase

NCT03456076 2017-004331-37 BO40336
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>= 18 Years	No

How does the ALINA clinical trial work? This clinical trial is recruiting people with a specific type of lung cancer called ‘non-small cell lung cancer’ or NSCLC that has been

completely removed by recent surgery. The removed lung cancer must be positive for a change in a protein called ‘ALK ’ (this is called ‘ALK-positive NSCLC’).

How do I take part in this clinical trial? If you think this clinical trial may be suitable for you and would like to take part, please talk to your doctor.

If your doctor thinks that you might be able to take part in this clinical trial, he/she may refer you to the closest clinical trial doctor who will give you all the information you need to make your decision about taking part in the clinical trial. You will also find the clinical trial locations at the top of this page.

Before starting the clinical trial, you will be told about any risks and benefits of taking part and what other treatments are available so that you may decide if you still want to take part. While taking part in the clinical trial, both men and women (who are able to become pregnant) will need use effective contraceptive methods or not have heterosexual intercourse for safety reasons (pregnant women cannot participate).

You will have some further tests and procedures to make sure you are a suitable candidate for this clinical trial. Some of these tests and procedures may be part of your regular medical care and may be done even if you do not take part in the clinical trial. If you have had some of the tests recently, they may not need to be done again.

What treatment will I be given if I join this clinical trial? The aim of this trial is to compare the effects, good or bad, of alectinib versus chemotherapy, which is currently the most common treatment for NSCLC after complete removal of the tumour by surgery. The trial will be comparing alectinib with chemotherapy to #nd out which is better at stopping the cancer from coming back after a complete removal by surgery.

Everyone who joins this clinical trial will be split into two groups randomly (like flipping a coin) and given one of the two different treatments:

- Either you will be given 4 capsules of alectinib to swallow 2 times a day for 2 years.
- Or you will be given 4 intravenous infusions of chemotherapy (the drug is slowly injected into your vein) once every 3 weeks for a total duration of 12 weeks.

How often will I be seen in follow-up appointments, and for how long? If you take part in this clinical trial, whichever treatment you are given, you could have up to 18 visits over the first 2 years to the clinical trial site for treatment, safety monitoring, and monitoring of your disease. Afterwards, you will have regular check-ups to monitor your disease every 24 weeks during years 3 to 5, and every year thereafter. Visits may last about 2-6 hours depending on the tests performed each time.

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What happens if I'm unable to take part in this clinical trial? If your specific cancer type does not match what this clinical trial is looking at and/or the results of your blood tests or any other tests are not in the range needed for the trial, you will not be able to take part in this clinical trial. Your doctor will suggest other treatments for your cancer that you can be given or other clinical trials that you may be able to take part in. You will not lose access to any of your regular care.

For more information about this clinical trial see the **For Expert** tab on this page or follow this link to ClinicalTrials.gov

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