ForPatients
by Roche

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

A study to look at how safe and how well different targeted therapies work in people with non-small cell lung cancer that has certain biomarkers

A Study to See How Well and How Safely Different Treatments Work in a Group of Participants With Non-Small Cell Lung Cancer (NSCLC)

Trial Status	Trial Runs In	Trial Identifier
Recruiting	3 Countries	NCT06624059 2024-511239-91-00 BO43249

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

Trial Summary:

The objective of this study is to evaluate the efficacy and/or safety of multiple therapies in patients with early-stage resectable NSCLC. Cohort B1 is a phase II cohort that will evaluate the safety, and efficacy of alectinib in combination with up to four cycles of platinum-based chemotherapy in the adjuvant setting post complete surgical resection. Cohort B2 is a phase II cohort that will evaluate the efficacy and safety of perioperative alectinib in combination with chemotherapy in the neoadjuvant setting.

Hoffmann-La Roche Sponsor	**Phase 3** Phase

NCT06624059 2024-511239-91-00 BO43249
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>=18 Years	No

1. Why is this study needed?

Non-small cell lung cancer (NSCLC) is the most common type of lung cancer. NSCLC usually develops in the tissues lining the lungs and can spread to nearby lymph nodes and other organs.

Surgery is the first treatment for people with NSCLC that can be removed. Treatments, such as chemotherapy, can also be given before surgery to shrink the cancer, and after surgery to reduce the risk of cancer growing back. However, these treatments may not always work for people with different types of NSCLC. So, new combinations of treatments for NSCLC are needed.

Some cancers have markers known as ‘biomarkers’. Healthy, non-cancerous cells do not have them. This means biomarkers can act as targets for cancer treatment – known as ‘targeted therapy’. Targeted therapy is a type of treatment that treats abnormal cells (e.g. cancer cells) in the body. It causes less harm to the normal cells.

This study is testing different targeted therapies alone or in combination with other drugs such as chemotherapy. They are being developed to treat NSCLC. The targeted therapies are experimental medicines. This means health authorities (like the U.S. Food and Drug Administration and European Medicines Agency) have not approved them to be given in combination with chemotherapy, or before surgery, for treating NSCLC that has a biomarker matching the targeted therapy.

This study aims to test how safe and how well targeted therapies work in people with matched-NSCLC that can be removed with surgery.

2. Who can take part in the study?

People of at least 18 years of age with NSCLC that can be or has been removed with surgery can take part in the study. They must be able to be given chemotherapy. Before a person can join the study, the doctor will check their NSCLC for a biomarker. It must match a targeted treatment in the study.

People may not be able to take part in this study if they have had certain treatments before. This includes a targeted therapy similar to the one being tested that matches their NSCLC. People may also not take part if they have certain health problems. These include liver, heart or lung diseases or certain infections. People who are pregnant, or currently breastfeeding cannot take part in the study.

3. How does this study work?

People will be screened to check if they are able to participate in the study. The screening period will take place from 1 to 2 months before the start of treatment.

Everyone in this study will join a treatment group that matches their NSCLC biomarker. They will be given a targeted therapy as a pill to be swallowed. Targeted therapy may be given before and/or after surgery. Standard chemotherapy will also be given before or after surgery as a drip into a vein (infusion).

This is an ‘open-label’ study. This means everyone involved, including the participant and the study doctor, will know the study treatment the participant has been given.

During this study, the study doctor will see participants regularly. They will see how well the treatment is working and any unwanted effects participants may have. Participants will have initial follow-up visits after completing the study treatment, during which the study doctor will check on the participant’s wellbeing. Participants will then have follow-up visits or phone calls regularly for as long as they agree to it, or until the study ends. Total time of participation in the study is up to around 10 years, including follow-up time, depending on the response to treatment and which group a participant is in. Participants have the right to stop study treatment and leave the study at any time, if they wish to do so.

4. What are the main results measured in this study?

The main results measured in the study will assess how safe and effective the treatment is. The number and seriousness of unwanted effects will be assessed in all treatment groups. Other results measured may be different between treatment groups.

Other key results measured in the study may include:

- The number of people with no detectable cancer left after treatment and surgery
- How long people live
- The time between no signs of NSCLC on scans or tests after treatment and the signs that it has come back
- The number of people without signs of NSCLC at 1, 2, 3, 4 and 5 years after treatment
- The number of people with less than one-tenth of their cancer left after treatment. It is compared to the amount of cancer they had before treatment
- How many people have a reduction of their cancer after treatment
- The time between starting treatment and NSCLC coming back, getting worse so that surgery cannot take place, or NSCLC spreading to nearby tissues or to other parts of the body
- The time between starting treatment and the start of certain unwanted effects
- The number of people who have targeted treatment before surgery and successfully have surgery without complications or delays
- How study treatment gets to different parts of the body, and how the body changes and gets rid of it
- How study treatment works in the body and the effects it has
- How a person’s health, cancer symptoms or unwanted effects of treatment impact their daily life and their ability to function and enjoy life

5. Are there any risks or benefits in taking part in this study?

Taking part in the study may or may not make participants feel better. But the information collected in the study can help other people with similar health conditions in the future.

It may not be fully known at the time of the study how safe and how well the study treatment works. The study involves some risks to the participant. But these risks are generally not greater than those related to routine medical care or the natural progression of the health condition. People interested in taking part will be informed about the risks and benefits, as well as any additional procedures or tests they may need to undergo. All details of the study will be described in an informed consent document. This includes information about possible effects and other options of treatment.

Risks associated with the study drugs Participants may have unwanted effects of the drugs used in this study. These unwanted effects can be mild to severe, even life-threatening, and vary from person to person. During this study, participants will have regular check-ups to see if there are any unwanted effects. Participants will be told about the known unwanted effects of targeted therapies given on their own or in combination with other drugs such as platinum-based chemotherapy, and possible unwanted effects based on human and laboratory studies or knowledge of similar medicines.

Known unwanted effects of platinum-based chemotherapy include throwing up, wanting to throw up, a low number of red blood cells, frequent watery stools, and hair loss. Known unwanted effects of an infusion include throwing up, wanting to throw up, a feeling of coldness that makes the body shiver, low or high blood pressure, fever, pain or discomfort in the head, frequent watery stools, shortness of breath, and cough.

The study medicine(s) may be harmful to an unborn baby. Women and men must take precautions to avoid exposing an unborn baby to the study treatment.