ForPatients
by Roche

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

A clinical trial to look at how alectinib and entrectinib each work to reduce certain signs of cancer compared with durvalumab in people with advanced non-small cell lung cancer with specific abnormal genes, and how safe alectinib and entrectinib are

A Study Evaluating the Efficacy and Safety of Multiple Therapies in Cohorts of Participants With Locally Advanced, Unresectable, Stage III Non-Small Cell Lung Cancer (NSCLC)

Trial Status	Trial Runs In	Trial Identifier
Recruiting	29 Countries	NCT05170204 2023-503920-14-00 BO42777

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 study will evaluate the efficacy and safety of multiple therapies in participants with locally advanced, unresectable, Stage III NSCLC with eligible biomarker status as determined by Version 8 of the American Joint Committee on Cancer/Union for International Cancer Control NSCLC staging system.

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

NCT05170204 2023-503920-14-00 BO42777
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>=18 Years	No

1. Why is the BO42777 clinical trial needed?

Non-small cell lung cancer (NSCLC) that has not spread in the body and cannot be removed by surgery is known as ‘locally advanced unresectable NSCLC’. The current standard treatment is chemoradiotherapy. This may be followed by treatment with a drug called durvalumab, depending on which country you live in. Sometimes NSCLC continues to get worse after standard treatment, so new treatments are needed.

Alectinib and entrectinib are treatments that can stop cancer from growing and spreading to other parts of the body. Alectinib and entrectinib target cancer cells that have certain changes (called mutations) in the *ALK* or *ROS1* genes. They have not yet been approved to treat locally advanced unresectable NSCLC.

This clinical trial aims to compare the effects, good or bad, of alectinib and entrectinib against durvalumab in people with locally advanced unresectable NSCLC with *ALK* or *ROS1* gene mutations.

2. How does the BO42777 clinical trial work?

This clinical trial is recruiting people with locally advanced unresectable NSCLC that has *ALK* or *ROS1* gene mutations. People can take part if they have been treated with at least two cycles of chemoradiotherapy within 6 weeks before starting the trial and their cancer has not gotten worse during or following chemoradiotherapy.

People who take part in this clinical trial (participants) will be given the clinical trial treatment alectinib or entrectinib for up to 3 years OR durvalumab for up to 1 year. The clinical trial doctor will see them every 2 weeks for the first 3 months, then once a month while being given treatment. These hospital visits will include checks to see how the participant responds to the treatment and any side effects they may have. Some visits may be conducted at the participant's home or local clinic (depending on the clinical trial doctor's instructions and different country's requirements). After the last dose of treatment, participants will be followed-up every 1 to 3 months at clinic visits, by telephone or through their medical records, for as long as they agree to it. The total time of participation in the clinical trial will depend on how the cancer is controlled by the trial treatment and could be more than 8 years. Participants can stop trial treatment and leave the clinical trial at any time.

3. What are the main endpoints of the BO42777 clinical trial?

The main clinical trial endpoint (the main result measured in the trial to see if the drug has worked) is the amount of time between the start of the trial and participants' cancer worsening.

The other clinical trial endpoints include:

- The amount of time between the start of the trial and cancer spreading in the brain or body
- The number of participants whose tumours have got smaller and the amount of time this lasts if disease then progresses
- How long participants live
- The amount of time between the start of the trial and participants' quality of life or cancer symptoms (cough, chest pain or shortness of breath) getting worse

- The number of participants with no worsening of, or improved, quality of life and cancer symptoms
- The number and seriousness of side effects

4. Who can take part in this clinical trial?

People can take part in this trial if they are at least 18 years old and are willing and able to use the device or apps provided for questionnaires.

People cannot take part in this trial if they have NSCLC that has spread in the body or that has certain other gene mutations. People may also not be able to take part in this trial if they have certain other medical conditions, such as heart conditions, liver disease or certain infections, have had or are receiving certain treatments, have ongoing side effects from previous cancer treatments, are involved in another clinical trial or are unable to swallow pills. People who are pregnant, breastfeeding or planning to become pregnant during or soon after the clinical trial also cannot take part.

5. What treatment will participants be given in this clinical trial?

Everyone who joins this clinical trial will be placed into a treatment group depending on which mutation is present in their lung cancer (*ALK* or *ROS1*), and will be given either:

Group A1 (participants with ALK-positive NSCLC)

- Alectinib given as oral pills twice daily with food for up to 3 years
- OR durvalumab given as infusions into the vein every 4 weeks for up to 1 year

Group A2 (participants with ROS1-positive NSCLC)

Note: Group A2 is now closed – no new participants will join this group.

- Entrectinib given as oral pills once daily with or without food for up to 3 years
- OR durvalumab given as infusions into the vein every 4 weeks for up to 1 year

Participants in each group (A1 or A2) will have an equal chance of receiving one of the targeted therapies or durvalumab. People in certain countries may be unable to join a specific treatment group due to the restrictions of the country they live in.

This is an open-label trial, which means everyone involved, including the participant and the clinical trial doctor, will know the clinical trial treatment the participant has been given.

6. Are there any risks or benefits in taking part in this clinical trial?

The safety or effectiveness of the experimental treatment or use may not be fully known at the time of the trial. Most trials involve some risks to the participant. However, it may not be greater than the risks related to routine medical care or the natural progression of

the health condition. People who would like to participate will be told about any risks and benefits of taking part in the clinical trial, as well as any additional procedures, tests or assessments they will be asked to undergo. All of these will be described in an informed consent document (a document that provides people with the information they need to decide to volunteer for the clinical trial).

Risks associated with the clinical trial drugs

Participants may have side effects (an unwanted effect of a drug or medical treatment) from the drugs used in this clinical trial. Side effects can be mild to severe, even life-threatening, and vary from person to person. Participants will be closely monitored during the clinical trial; safety assessments will be performed regularly.

Alectinib, entrectinib and durvalumab

Participants will be told about the known side effects of alectinib, entrectinib or durvalumab and possible side effects based on human and laboratory studies or knowledge of similar drugs. Alectinib or entrectinib will be given as a pill to be swallowed, and durvalumab will be given as an infusion into the vein (intravenous infusion). Participants will be told about any known side effects of swallowing pills or intravenous infusions.

Potential benefits associated with the clinical trial

Participants' health may or may not improve from participation in the clinical trial. Still, the information collected may help other people with similar medical conditions in the future.