ForPatients
by Roche

Cancro del polmone a piccole cellule

A clinical trial to compare atezolizumab plus chemotherapy with or without tiragolumab in people with extensive stage small cell lung cancer

A Study of Atezolizumab Plus Carboplatin and Etoposide With or Without Tiragolumab in Patients With Untreated Extensive-Stage Small Cell Lung Cancer

Trial Status	Trial Runs In	Trial Identifier
Completata	23 Countries	NCT04256421 2022-502988-37-00 GO41767

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Official Title:

A Phase III, Randomized, Double-Blind, Placebo-Controlled Study of Atezolizumab Plus Carboplatin and Etoposide With or Without Tiragolumab (Anti-Tigit Antibody) in Patients With Untreated Extensive-Stage Small Cell Lung Cancer

Trial Summary:

This study will evaluate the efficacy of tiragolumab plus atezolizumab and carboplatin and etoposide (CE) compared with placebo plus atezolizumab and CE in participants with chemotherapy-naive extensive-stage small cell lung cancer (ES-SCLC). Eligible participants will be stratified by Eastern Cooperative Oncology Group (ECOG) Performance Status (0 vs. 1), LDH (</= upper limit of normal [ULN] vs. > ULN), and presence or history of brain metastasis (yes vs. no) and randomly assigned in a 1:1 ratio to receive one of the following treatment regimens during induction phase: * Arm A: Tiragolumab plus atezolizumab plus CE * Arm B: Placebo plus atezolizumab plus CE Following the induction phase, participants will continue maintenance therapy with either atezolizumab plus tiragolumab (Arm A) or atezolizumab plus placebo (Arm B).

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Phase 3
Phase

NCT04256421 2022-502988-37-00 GO41767
Trial Identifiers

Eligibility Criteria:

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Gender	Age	Healthy Volunteers
All	#18 Years	No

Why is this study needed? Small cell lung cancer (SCLC) is a rare and fast-growing type of lung cancer that is usually seen in smokers. It occurs when abnormal cells in the lung grow uncontrollably, forming a lump or mass. SCLC is usually seen towards the centre of the lung. In the extensive stage, the cancer spreads to the other side of the chest, affecting the other lung and lymph nodes, and also other parts of the body. Hence, there is a constant need to find new combinations of treatments to deliver better long-term survival.

This study is testing the combination of tiragolumab with atezolizumab and chemotherapy for the treatment of extensive-stage SCLC. Tiragolumab is an experimental drug, which means health authorities (like the U.S. Food and Drug Administration and European Medicines Agency) have not approved it yet. Atezolizumab in combination with chemotherapy, is approved by health authorities worldwide as a treatment for extensive-stage SCLC that has not yet been treated.

This study aims to compare the effects of tiragolumab plus atezolizumab and chemotherapy versus placebo plus atezolizumab and chemotherapy in people with SCLC. Placebo is a medicine without any active ingredients.

Who can take part in the study? People who were at least 18 years old with extensive-stage SCLC took part in this study. People could not take part in this study if their cancer has spread to certain critical parts of the brain and spinal cord. Women who were pregnant, or breastfeeding could not participate in the study.

How does this study work? Participants were screened to determine their eligibility to participate in the study. The screening period took place for about 28 days before the start of treatment.

Everyone who joined this study were split into 2 groups (Groups A and B) randomly (like flipping a coin). Participants are receiving either tiragolumab plus atezolizumab and chemotherapy (Group A), or placebo plus atezolizumab and chemotherapy (Group B), as a drip into the vein, once every 3 weeks. Treatment will continue until participants are not experiencing benefits from the treatment, their cancer worsens, or they experience any unacceptable unwanted effects.

This is a ‘placebo-controlled’ study. This means that participants were put in a group that received tiragolumab or a group that received ‘placebo’. All participants received atezolizumab and chemotherapy. Comparing results from the two different groups helps researchers know if any observed changes result from the study medicine (tiragolumab) or occur by chance. This is a double-blinded study. This means that neither the participants in the study nor the team running it knew which treatment is being given until the study is over. This is done to make sure that the results of the treatment are not affected by what

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people expect from the received treatment. However, the study doctor can find out which group the participant is in, if the participant's safety is at risk.

During this study, the study doctor sees participants every 3 weeks to see how well the treatment is working and any unwanted effects participants may have. After study treatment ends, they have follow-up visits or were contacted by telephone every 6 months to check on the participant's well-being. Total time of participation in the study is expected to be around 72 months depending on how the cancer responds to treatment. Participants have the right to stop study treatment and leave the study at any time, if they wish to do so.

What are the main results measured in this study? The main results measured in the study are to find out the approximate time from the start of treatment until the first occurrence of cancer worsening or participants dying due to any cause and also how long participants live. Other key results measured in the study include:

- How many people have a reduction of their cancer after treatment.
- How much time there is between the person's cancer first responding to treatment and the cancer getting worse.
- The time it takes for a person to have a significant worsening in physical health and quality of life
- How the participant's health and functioning are impacted by the treatment
- Number of participants with unwanted effects
- How well the body processes tiragolumab and atezolizumab
- Number of participants whose bodies produce proteins that work against tiragolumab and atezolizumab

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 participants. People interested in taking part were 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 had regular check-ups to see if there are any unwanted effects.

Tiragolumab Participants were told about the known unwanted effects of tiragolumab, and possible unwanted effects based on human and laboratory studies or knowledge

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of similar medicines. Known unwanted effects include but not limited to: reaction to the infusion, inflammation of the liver, low levels of red blood cells (anemia), itching of the skin (pruritus), joint pain (arthralgia), decreased appetite, rash, increases in abnormal liver enzymes, decrease in potassium levels (hypokalemia), infection of the lung (pneumonia) and belly pain.

Tiragolumab, atezolizumab and placebo are given as a drip into the vein. Known unwanted effects include but not limited to: fever, chills, shortness of breath, rash, nausea, and changes in blood pressure.

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.

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

Trial-identifier: NCT04256421

Inclusion Criteria:

- Histologically or cytologically confirmed extensive-stage small cell lung cancer (ES-SCLC)
- No prior systemic treatment for ES-SCLC
- Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1
- Measurable disease, as defined by Response Evaluation Criteria in Solid Tumors version 1.1 (RECIST v1.1)
- Adequate hematologic and end-organ function
- Treatment-free for at least 6 months since last chemo/radiotherapy, among those treated (with curative intent) with prior chemo/radiotherapy for limited-stage SCLC

Exclusion Criteria:

- Symptomatic or actively progressing central nervous system (CNS) metastases
- Malignancies other than small cell lung cancer (SCLC) within 5 years prior to randomization, with the exception of those with a negligible risk of metastasis or death treated with expected curative outcome
- Active or history of autoimmune disease or immune deficiency
- History of idiopathic pulmonary fibrosis, organizing pneumonia, drug-induced pneumonitis, or idiopathic pneumonitis, or evidence of active pneumonitis on screening chest computed tomography (CT) scan
- Positive test result for human immunodeficiency virus (HIV)
- Active hepatitis B or hepatitis C
- Severe infection at the time of randomization
- Treatment with any other investigational agent within 28 days prior to initiation of study treatment
- Prior treatment with CD137 agonists or immune checkpoint blockade therapies, anti-cytotoxic T lymphocyte-associated protein 4 (anti-CTLA-4), anti-TIGIT, anti-PD-1, and anti-PD-L1 therapeutic antibodies
- Treatment with systemic immunostimulatory agents within 4 weeks or 5 drug elimination half-lives prior to randomization

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