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.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory and mediastinal neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON54967

Source
ToetsingOnline

Brief title
GO41767 / SCYCRAPER2

Condition

- Respiratory and mediastinal neoplasms malignant and unspecified
- Respiratory tract neoplasms

Synonym

lung cancer, Small cell lung cancer

Research involving
Human

Sponsors and support

Primary sponsor: Roche
Source(s) of monetary or material Support: Sponsor

Intervention

Keyword: Atezolizumab, Phase III, Small cell lung cancer, Tiragolumab

Outcome measures

Primary outcome

-Progression-free survival (PFS) after randomization, defined as the time from randomization to the first occurrence of disease progression or death from any cause (whichever occurs first), as determined by the investigator according to Response Evaluation Criteria in Solid Tumors (RECIST) v1.1. (in the PAS)

-Overall survival (OS) after randomization, defined as the time from randomization to death from any cause. (in the PAS)

Up to 50 months

Secondary outcome

-Confirmed objective response rate (ORR), defined as the proportion of patients with a complete response (CR) or partial response (PR) on two consecutive occasions => 4 weeks apart, as determined by the investigator according to RECIST v1.1. (in the PAS and FAS)

-Duration of response (DOR) for patients with confirmed objective response, defined as the time from the first occurrence of a documented objective

response to disease progression or death from any cause (whichever occurs

first), as determined by the investigator according to RECIST v1.1 (in the PAS

and FAS)

-PFS rates at 6 months and at 12 months (PAS and FAS)

-OS rates at 12 months and 24 months (PAS and FAS)

-Time to sustained deterioration (TTSD) in patient-reported physical

functioning and global health status, as measured by the European Organisation

for the Research and Treatment of Cancer (EORTC) Quality-of-Life Questionnaire

Core (QLQ-C30)/ (PAS and FAS)

Up to 50 months

Study description

Background summary

The current standard first-line treatment for patients with ES-SCLC is chemotherapie. Despite the survival benefit observed with this regimen, median survival remains at approximately 8 months, leaving considerable room for improvement in outcomes.

Tumor-cell killing by cytotoxic chemotherapy can reasonably be expected to expose the immune system to high levels of tumor antigens. Therefore, invigorating tumor-specific T-cell immunity by inhibiting PD-L1/PD-1 signaling and TIGIT/PVR may result in deeper
and more durable responses compared with standard chemotherapy alone
Evaluating the safety and efficacy of these treatment combinations in patients with SCLC will enable future tests of this hypothesis.
In light of these observations, this study (Study GO41767) is designed to evaluate whether the anti-tumor effect of the combination of atezolizumab plus CE (IMpower133 regimen) can be enhanced by adding tiragolumab in treating patients with
chemotherapy-naive ES-SCLC.

Refer to section 1 of the protocol for a more elaborate background and study rationale.

Study objective

The objective for this study is to evaluate the efficacy of tiragolumab plus atezolizumab and carboplatin and etoposide (CE) compared with placebo plus atezolizumab and CE in patients with untreated extensive-stage small cell lung cancer (ES-SCLC) on the basis of progression free survival (PFS) and overall survival (OS) in primary analysis set (PAS), patients without presence or history of brain metastases at baseline.

Study design

This is a randomized, Phase III, global, multicenter, double-blinded, placebo-controlled study designed to evaluate the safety and efficacy of tiragolumab in combination with atezolizumab and CE compared with treatment with placebo in combination with atezolizumab and CE in patients who have ES-SCLC and are chemotherapy naive for their extensive-stage disease. After screening, there are 3 phases in this study: induction, maintenance and follow-up.

The study design is elaborately described in figure 1 and appendix 1 of the protocol.

Intervention

Eligible patients will be randomized 1:1 to receive one of the following treatment regimens during the induction phase
-Arm A: tiragolumab plus atezolizumab and CE
-Arm B: placebo plus atezolizumab and CE

Induction treatment will be administered on a 21-day cycle for 4 cycles. Following the induction phase, patients will continue maintenance therapy with either atezolizumab plus tiragolumab (Arm A) or atezolizumab plus placebo (Arm B).

Study burden and risks

The general burden on the patient consists, among other things, of blood samples (every cycle), possible tumor biopsy, the use of the investigational products (every cycle) with which various possible adverse effects are associated.

Contacts

Public
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Age > 18 years
- Eastern Cooperative Oncology Group performance status of 0 or 1
- Histologically or cytologically confirmed ES-SCLC
- No prior systemic treatment for ES-SCLC
- For patients who have received prior chemoradiotherapy for limited-stage SCLC: must have had treatment with curative intent and a treatment-free interval of at least 6 months between the last dose/cycle of chemotherapy, thoracic radiotherapy, or chemoradiotherapy and the diagnosis of ES-SCLC
- Measurable disease, as defined by Response Evaluation Criteria in Solid Tumors version 1.1
- Submission of a pre-treatment tumor tissue sample

- Adequate hematologic and end-organ function

Exclusion criteria

- Symptomatic or actively progressing CNS metastases
- Spinal cord compression not definitively treated with surgery and/or radiation, or previously diagnosed and treated spinal cord compression without evidence that disease has been clinically stable for > 1 week prior to randomization
- Leptomeningeal disease
- Uncontrolled pleural effusion, pericardial effusion, or ascites requiring recurrent drainage procedures, hypercalcemia
- Known clinically significant liver disease
- Malignancies other than 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
- Treatment with any other investigational agent with therapeutic intent within 28 days prior to randomization
- Pregnancy or breastfeeding, or intention of becoming pregnant during study treatment or within 5 months after the final dose of atezolizumab or tiragolumab or for 6 months after the final dose of carboplatin or etoposide.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	27-08-2020
Enrollment:	15
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Tecentriq
Generic name:	Atezolizumab
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	Tiragolumab
Generic name:	Tiragolumab

Ethics review

Approved WMO Date:	19-03-2020
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	05-06-2020
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	05-08-2020
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	27-10-2020
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO	

Date:	16-12-2020
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	30-12-2020
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	26-01-2021
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	26-03-2021
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	08-06-2021
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	14-07-2021
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	24-09-2021
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	25-10-2021
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek

	(Assen)
Approved WMO Date:	09-12-2021
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	27-12-2021
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	01-06-2022
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	30-08-2022
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	10-11-2022
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	02-12-2022
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	14-01-2023
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	21-05-2023

Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	10-08-2023
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2019-003301-97-NL
ClinicalTrials.gov	NCT04256421
CCMO	NL72355.056.20