A phase III prospective double blind placebo controlled randomized study of adjuvant MEDI4736 in completely resected non-small cell lung cancer

Published: 29-03-2016
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This study has been transitioned to CTIS with ID 2024-517856-36-00 check the CTIS register for the current data. To assess in comparison to placebo, the impact of adjuvant therapy with MEDI4736 given by intravenous infusion for one year on the...

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

Summary

ID

NL-OMON54539

Source
ToetsingOnline

Brief title
NVALT 24

Condition

- Respiratory and mediastinal neoplasms malignant and unspecified

Synonym
lung cancer, lung carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Stichting NVALT studies

Source(s) of monetary or material Support: NCIC (National Cancer Institute of Canada)

Intervention

Keyword: MEDI4736, NSCLC, phase III

Outcome measures

Primary outcome

To assess in comparison to placebo, the impact of adjuvant therapy with MEDI4736 given by intravenous infusion for one year on the disease free survival of patients with completely resected (stage IB > 4cm, stage II or IIIA), non-small cell lung cancer that is PD-L1 positive.

Secondary outcome

Disease free survival in all randomized patients.

To compare the overall survival in the MEDI4736 arm to the placebo arm in patients with NSCLC that is PD-L1 positive.

To compare the overall survival in the MEDI4736 arm to the placebo arm in all randomized patients.

To compare lung cancer specific survival in the MEDI4736 arm to the placebo arm for patients with PD-L1+ NSCLC as well as all randomized patients.

• To evaluate the nature, severity, and frequency of toxicities, between arms.

• To evaluate the quality of life between the two arms in PD-L1+ patients and in all randomized patients.

• To determine the incremental cost effectiveness and cost utility ratios for MEDI4736.

• To evaluate the prognostic and predictive significance of PD-L1 expression.

• To evaluate changes in plasma/serum cytokines and other blood and tissue

based biomarkers after treatment with MEDI4736 and at the first disease event

(relapse or new invasive primary malignancy).

• To explore polymorphisms that may be associated with outcomes

Study description

Background summary

Despite evidence of clinical benefit has been observed in non-small cell lung cancer (NSCLC) patients treated with adjuvant chemotherapy, patients still relapse and estimated 5-year survival is 50-60%. There is need for new treatments to improve survival of these patients. MEDI4736 is a PD-L1 inhibitor, inhibition of the PD-1 immune checkpoint pathway has been shown to induce durable clinical response.
The purpose of this study is to find out whether it is better to receive MEDI4736, or better to receive no further treatment, after surgery (and possibly chemotherapy).

Study objective

This study has been transitioned to CTIS with ID 2024-517856-36-00 check the CTIS register for the current data.

To assess in comparison to placebo, the impact of adjuvant therapy with MEDI4736 given by intravenous infusion for one year on the disease free survival of patients with completely resected (stage IB > 4cm, stage II or IIIA), non-small cell lung cancer that is PD-L1 positive.

Study design

Phase III, multi-centre, prospective, randomized, placebo-controlled trial
Randomization will be 2:1 to the active treatment arm
Stratification by stage, PD-L1 expression,adjuvant platinum based chemotherapy (yes/no), centre, nodal sampling/dissection conducted in accordance with the ESTS guidelines (yes/no)

Intervention

MEDI4736 or placebo, via IV infusion in cycles of 4 weeks for one year.

Study burden and risks

On several days during the study patients will undergo the following assessments:
physical examination
questionnaires (EORTC QLQ C-30-LC13, EQ-5D)
ECG
lung function test
vital signs (blood pressure, pulse)
blood and urine test
CT scan, if applible CT/MRI brain
pregnancy test (if applicable)
echocardiography or MUGA scan (if applicable, once)

Contacts

Public
Stichting NVALT studies

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Histologically confirmed NSCLC (post-operatively stage IB, II or IIIA)
Complete surgical resection
ECOG PS 0-1
Adequate bone marrow, hepatic and renal function
Age 18 years or older
After 600 randomizations, only PD-L1 positive patients will be enrolled

Exclusion criteria

combination of small cell and non-small cell lung cancer or pulmonary carcinoid tumour
autoimmune disease
untreated and/or uncontrolled cardiovascular conditions and/or symptomatic cardiac dysfunction
Pregnant or lactating women
Pre-operative chemotherapy
pre- or post operative RT

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:	Recruiting
Start date (anticipated):	26-04-2017
Enrollment:	50

Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	NA
Generic name:	onbekend

Ethics review

Approved WMO Date:	29-03-2016
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	30-06-2016
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	09-03-2017
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	23-03-2017
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	04-08-2017
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	09-08-2017
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	12-01-2018

Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	23-01-2018
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	09-08-2018
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	07-12-2018
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	04-03-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	15-03-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	07-10-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	11-10-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	12-12-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	11-02-2023

Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	17-02-2023
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	04-04-2023
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	02-08-2023
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	07-08-2023
Application type:	Amendment
Review commission:	METC NedMec

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
EU-CTR	CTIS2024-517856-36-00
EudraCT	EUCTR2014-004946-83-NL
ClinicalTrials.gov	NCT02273375
CCMO	NL54852.031.16