

# 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...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Respiratory and mediastinal neoplasms malignant and unspecified
<b>Study type</b>	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 applicable CT/MRI brain

pregnancy test (if applicable)

echocardiography or MUGA scan (if applicable, once)

## Contacts

### Public

Stichting NVALT studies

Luijbenstraat 15

's-Hertogenbosch 5211BR

NL

### Scientific

Stichting NVALT studies

Luijbenstraat 15

's-Hertogenbosch 5211BR

NL

## 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

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