MEDIASTinal staging of non-small cell lung cancer by endobronchial and endoscopic ultrasonography with or without additional surgical mediastinoscopy

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Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21273

Bron
Nationaal Trial Register

Verkorte titel
MEDIASTrial

Aandoening

Non-small cell lung carcinoma, mediastinal staging, endosonography, mediastinoscopy, thoracic surgery

Ondersteuning

Primaire sponsor: Máxima Medical Center
Overige ondersteuning: ZonMw, project number: 843004109

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Unforeseen N2 disease

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: NSCLC patients with increased risk of mediastinal lymph node metastases should undergo cervical mediastinoscopy to rule out mediastinal nodal spread, despite negative endobronchial and/or endoscopic ultrasound (EBUS/EUS-B). It is unknown whether additional mediastinoscopy can be omitted without compromising important outcomes.

Research question: Will omitting cervical mediastinoscopy in patients with negative staging by EBUS/EUS-B be non-inferior to the strategy with additional mediastinoscopy regarding the occurrence of unforeseen N2 disease after definite surgery and be superior regarding cost-effectiveness?

Study design: Multicenter parallel randomized trial comparing two diagnostic strategies (with or without mediastinoscopy) for mediastinal staging in patients with suspected NSCLC. All randomized patients will be followed up for 2 years.

Study population: Patients are eligible for inclusion in this trial when they meet the following eligibility criteria:

1. Diagnosed (pathological proof) or suspected (based on CT and FDG-PET) with NSCLC.

2. CT and FDG-PET scan have excluded distant metastasis or an irresectable primary tumour.

3. One of the criteria defining the need for mediastinal staging are met according to the European and Dutch guidelines:

- PET/CT of the chest demonstrates CT-enlarged or FDG-PET avid hilar or mediastinal lymph

nodes.

- CT demonstrates central location of the primary tumour

- FDG-PET demonstrates a PET non avid primary tumour

- Peripheral lung tumours larger than 3cm on CT

Doel van het onderzoek

Mediastinal staging of NSCLC by EBUS/EUS-B with and without additional cervical mediastinoscopy are both effective diagnostic strategies for assessment of mediastinal lymph node metastases. However, omitting mediastinoscopy comprises no extra waiting time until definite surgery, no additional required general anaesthesia and hospital admission, and may be associated with lower morbidity and comparable survival. Therefore, this strategy may reduce health care costs and increase quality of life.

Onderzoeksopzet

Baseline, 1 week after mediastinoscopy (as performed), 2 weeks, 4 weeks, 3 months, 6 months, 12 months and 24 months after start treatment.

Onderzoeksproduct en/of interventie

Intervention: After negative EBUS/EUS-B patients will undergo immediate anatomic resection of the primary tumour.

Usual care: According to current national and international guidelines, patients will first undergo cervical mediastinoscopy after negative EBUS/EUS-B.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients underwent systematic EBUS (+ EUS-B) to evaluate mediastinal lymph nodes including tissue sampling with negative biopsy results.

2. Patients should be fit enough to undergo resection of the primary tumour.

3. Patients should be able to undergo cervical mediastinoscopy.

4. Age of 18 years or older and able to give informed consent and fill out questionnaires.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. PET/CT demonstrates bulky N2-3 disease.

2. The combination of a highly suspicious as well as irresectable mediastinal lymph node.

3. Non-correctable coagulopathy.
4. Insufficient comprehension of the Dutch language to understand the trial information and to complete the questionnaires during follow-up period.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	11-07-2017
Aantal proefpersonen:	360
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	06-07-2017
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 52981
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6344
NTR-old	NTR6528
CCMO	NL60692.015.17
OMON	NL-OMON52981

Resultaten