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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21273

Source
Nationaal Trial Register

Brief title
MEDIASTrial

Health condition

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

Sponsors and support

Primary sponsor: Máxima Medical Center
Source(s) of monetary or material Support: ZonMw, project number: 843004109

Intervention

Outcome measures

Primary outcome

Unforeseen N2 disease

Secondary outcome

1. Hospitalization

2. Cost-effectiveness and cost-utility

3. Morbidity: the combination of major morbidity and 30-day mortality

4. Overall 2-year survival

5. Quality of life

Study description

Background summary

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

Study objective

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.

Study design

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

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-07-2017
Enrollment:	360
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	06-07-2017
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 52981
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

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

Study results