MEDIASTINAL STAGING OF NON SMALL CELL LUNG CANCER BY ENDOBRONCHIAL AND ENDOSCOPIC ULTRASONOGRAPHY WITH OR WITHOUT ADDITIONAL SURGICAL MEDIASTINOSCOPY (MEDIASTrial)

Published: 15-06-2017
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Omitting mediastinoscopy improves cost-effectiveness and cost-utility of NSCLC staging, despite a slightly lower metastatic nodal detection rate.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory tract neoplasms
Study type	Interventional

Summary

ID

NL-OMON52981

Source
ToetsingOnline

Brief title
MEDIASTrial

Condition

- Respiratory tract neoplasms

Synonym
lung cancer, non-small cell lung cancer

Research involving
Human

Sponsors and support

Primary sponsor: Maxima Medisch Centrum
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Endosonography, Mediastinal staging, Mediastinoscopy, Non-small cell lung cancer

Outcome measures

Primary outcome

Primary: unforeseen N2 rate.

Secondary outcome

Secondary: a) health care utilization and costs; b) composite outcome of major

morbidity plus 30-day mortality; c) overall and disease-free survival; d)

disease-specific and generic quality of life.

Study description

Background summary

Non-small cell lung cancer (NSCLC) patients with increased risk of mediastinal lymph node metastases (N2-3) should undergo mediastinoscopy to rule out mediastinal nodal spread, despite negative endobronchial and/or endoscopic ultrasound (EBUS/EUS). It is unknown whether additional mediastinoscopy can be omitted without compromising important outcomes.

Study objective

Omitting mediastinoscopy improves cost-effectiveness and cost-utility of NSCLC staging, despite a slightly lower metastatic nodal detection rate.

Study design

Randomized trial comparing mediastinal staging strategies with and without mediastinoscopy.

Intervention

Usually mediastinoscopy will be performed first. Patients without metastatic nodal spread will undergo subsequent anatomic resection of the primary tumour and mediastinal lymph node dissection. The intervention will be that patients will directly undergo anatomic resection of the primary lung tumour including surgical mediastinal lymph node dissection, without mediastinoscopy first.

Study burden and risks

Patients who will be randomized to the intervention, will not undergo mediastinoscopy, thereby not exposing them to risks related to this surgery (0.2% mortality, 5.2% major morbidity). On the other hand, some patients (about 9%) randomized to the intervention arm will undergo anatomic resection of the primary tumour despite having N2 disease. Surgical risks are low (2.1% mortality, 12.2% major morbidity) and almost all those patients will have minimal N2 disease with survival rates comparable to patients with N1 disease. All study participants will be followed up according to standard follow up schedules, although with additional questionnaires at 5 points in time.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients with (suspected) NSCLC without distant metastases and suspected metastatic nodal spread on PET or CT scan; or a non PET-avid or centrally located tumour or a peripheral tumour >3 centimeters diameter. Previous EBUS/EUS has shown negative biopsy results.

Exclusion criteria

Not eligible are patients with: a) highly suspected bulky mediastinal nodal disease; b) high suspicion of single level N2-3 metastasis defined by specific PET and EBUS/EUS characteristics; c) suspected non-resectable N2 disease; d) insufficient comprehension of the dutch language.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-07-2017
Enrollment:	356

Type:	Actual

Ethics review

Approved WMO Date:	15-06-2017
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	24-07-2017
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	25-09-2017
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	05-04-2018
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	11-06-2018
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	17-01-2022
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	12-12-2022
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 21273
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL60692.015.17
OMON	NL-OMON21273

Study results

Date completed: 01-04-2023

Actual enrolment: 356

Summary results
Trial is onging in other countries