Evaluation of molecular sputum test diagnostic for lung cancer

Published: 26-11-2008
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Establish the clinical value of a molecular sputum test for the diagnosis of lung cancer.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory tract neoplasms
Study type	Observational non invasive

Summary

ID

NL-OMON38180

Source
ToetsingOnline

Brief title
Lung cancer sputum test

Condition

- Respiratory tract neoplasms

Synonym
bronchus carcinoma; lung cancer

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: KWF

Intervention

Keyword: cancer, lung, molecular analysis, sputum

Outcome measures

Primary outcome

Primary research variables

A) Establish effect of prolonged sputum sampling on sensitivity for diagnosis of lung cancer.

B) Establish clinical sensitivity and specificity of molecular sputum test for the diagnosis of lung cancer in symptomatic patients, and comparison of molecular test with cytological examination.

C) Establish clinical sensitivity and specificity of molecular sputum test for early diagnosis of lung cancer

Secondary outcome

A) Establish in subpopulation analysis of exhaled air.

B) Establish in subpopulation analysis molecular markers in blood for comparison with sputum.

Study description

Background summary

Background.
Lung cancer is the most fatal cancer in the western world. The 5 year survival is about 12%. Whether secondary prevention by high resolution CT (HRCT screening, NELSON study) will reduce mortality is not known yet. Disadvantages of this method are the high costs, and low specificity. Possibly molecular sputum analysis may be used to identify people high risk at high risk for or diagnosis of lung cancer.

Study objective

Establish the clinical value of a molecular sputum test for the diagnosis of lung cancer.

Study design

In a population of people with increased risk for the diagnosis of lung cancer (COPD) and in patients in the work up for the diagnosis of *lung cancer* sputum will be collected for a period of 9 days, pooled in samples of 3 days, leading to 3 sequential samples in each patient. Molecular analysis and cytological will be performed on the sputum samples in a blinded fashion.
A) Sputum of 3, 6 and 9 days will be used to determine the effect of this sampling on the sensitivity for diagnosis of lung cancer.
B) Comparison of the sputum analysis from lung cancer patients with COPD will reveal clinical sensitivity and specificity. The test outcome will be compared with cytological analysis.
C) The same test will be performed on samples from a sputum bank collected in the scope of the NELSON study of first round participants. This sputum bank has been collected and largely exits of people at risk and a limited number of asymptomatic lung cancer patients.

Study burden and risks

Risk estimation The risk of this study is estimated to be neglectable. The contribution of the patients is minor, as this consists of sputum collection and posting the box with 3 sampling vials.
Exhaled air risk is neglectable. For subgroup also additional venous blood puncture, performed for routine medical care.

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 suspicious of lung cancer;
Patients with progression of lung cancer after treatment

Exclusion criteria

No

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-05-2009

Enrollment:	600
Type:	Actual

Ethics review

Approved WMO Date:	26-11-2008
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-10-2010
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	08-08-2011
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-07-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
CCMO	NL22206.029.08