Tumormarkers in diagnostics and follow up of lungcarcinoma

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Respiratory and mediastinal neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON47860

Source
ToetsingOnline

Brief title
Tumor markers and lungcarcinoma

Condition

- Respiratory and mediastinal neoplasms malignant and unspecified
- Respiratory tract neoplasms

Synonym
lungcancer, lungcarcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis
Source(s) of monetary or material Support: Voor een onderdeel van dit onderzoek is een subsidie aanvraag gedaan bij NWO. Uitsluitsel in december 2016,Maxima Medisch Centrum;Catharina Ziekenhuis en Roche Diagnostics Nederland ,Roche Diagnostics

Nederland

Intervention

Keyword: molecular tumor marker, Non small cell lung cancer, protein tumor marker, Small cell lung cancer

Outcome measures

Primary outcome

Diagnostic properties of the single markers and various combination of markers

for diagnosis of NSCLC and SCLC.

Secondary outcome

see study protocol, section 'studieopzet/eindpunten'

Study description

Background summary

Following current Dutch guidelines, lung cancer is diagnosed using chest Xray, CT-scan or PET-CT and based on cytology or histology of tumor cells. Recent studies show that tumor markers can have added value in diagnosing lung cancer and in differentiating between small and non-small cell carcinoma (SCLC and NSCLC). In addition, tumor markers may have a place in following the effect of therapy. Differentiating NSCLC from SCLC with current diagnostics can be time-consuming and difficult while this differentiation is important for prognosis and choice of therapy. Aims of this study are to investigate, in a Dutch multi-center study, whether tumormarkers have clinical value in diagnosing, differentiation and treatment of lung cancer and in monitoring response to therapy.

Study objective

This study aims to prospectively evaluate the diagnostic properties and clinical value of the protein tumor markers CEA, CA15.3, Cyfra21.1, HE4, NSE, proGRP en SCC and the molecular tumormarkers EGFR, ALK, KRAS and BRAF in diagnosing, and monitoring of lung tumors. The hypothesis is investigated that a correct diagnosis (including subclassification of the tumor) and prognosis can be made more rapidly and that monitoring tumor development in response to therapy is more precise when adding tumormarkers to the follow up. The data

gathered in the study is used to program decision support and predictive algorithms.

Study design

prospective, observational study

Study burden and risks

No extra risk.
Small burden: per patient 30 ml of blood is drawn (1 to 21 times during max. 60 months).

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 suspected of having lung cancer that are refered to the pulmonolgy department of one of the participating hopsitals
18 years of age or older

Exclusion criteria

Aged under 18 years

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	17-07-2017
Enrollment:	1500
Type:	Actual

Ethics review

Approved WMO Date:	23-01-2017
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	05-04-2017

Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	30-07-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	01-02-2019
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	11-02-2019
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	13-11-2019
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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: 26180
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL58985.100.16
OMON	NL-OMON26180