Longmerkerstudie

Published: 24-12-2020
Last updated: 15-05-2024

The hypothesis investigated is 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 tumor markers to the...

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

Summary

ID

NL-OMON26180

Source
NTR

Brief title
Longmerkerstudie

Condition

- Respiratory and mediastinal neoplasms malignant and unspecified

Health condition

Lung carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Catharina Ziekenhuis Eindhoven, NWO, Catharina Onderzoeksfonds, Roche Diagnostics Nederland
Source(s) of monetary or material Support: Secondary funding (NWO or KNAW), Tertiary funding (other than primary and secondary funding, e.g. 'collecting box' funds, European Union, line ministries and companies)

Intervention

- Other intervention

Explanation

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 X-ray, 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 prospective Dutch multi-center study, whether molecular and protein tumor markers have clinical value in diagnosing, differentiation and treatment of lung cancer and in monitoring response to therapy.

Study objective

The hypothesis investigated is 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 tumor markers to the follow up. The data gathered in the study is used to program decision support and predictive algorithms.

Study design

- All patients: before diagnosis of the disease - Subset of the patients for follow-up: 1. During the diagnostic phase, before initiation of the treatment 2. 2-3 weeks after blood sample 1 3.

2-3 weeks after blood sample 2 4. 4-6 weeks after blood sample 3 5. 2-3 months after blood sample 4 6. 2-3 months after blood sample 5 7. 2-3 months after blood sample 6

Intervention

None

Contacts

Public
Catharina Hospital Eindhoven, Maxima Medisch Centrum and University of Technology Eindhoven
Esther Visser

040 239 8640
Scientific
Catharina Hospital Eindhoven, Maxima Medisch Centrum and University of Technology Eindhoven
Esther Visser

040 239 8640

Eligibility criteria

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

Inclusion criteria

- Patients with suspected lung cancer - Aged 18 years or above

Exclusion criteria

Aged under 18 years

Study design

Design

Study phase:	N/A
Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-07-2017
Enrollment:	1500
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Plan description
N/A

Ethics review

Approved WMO

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

Postbus 2500
3430 EM Nieuwegein
088 320 8784
info@mec-u.nl

Study registrations

Followed up by the following (possibly more current) registration

ID: 47860
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL9146
CCMO	NL58985.100.16
OMON	NL-OMON47860

Study results

Summary results
DOI: 10.1016/j.jmoldx.2019.05.003
DOI: 10.18632/oncotarget.27664
DOI: 10.1016/j.jmoldx.2021.01.003
DOI: 10.1016/j.ctarc.2021.100410
DOI: 10.1016/j.ctarc.2021.100449