Longkankernet implementation ctDNA Analysis

Published: 17-05-2021
Last updated: 04-04-2024

Targeted therapies guided by molecular diagnostics have become a standard treatment of lung cancer. Nowadays, tumour tissue is required to assess the molecular characteristics of the tumour. However, the procedures to obtain tissue are invasive and...

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

Summary

ID

NL-OMON50777

Source
ToetsingOnline

Brief title
LICA

Condition

- Respiratory and mediastinal neoplasms malignant and unspecified

Synonym
Lung cancer; non-small cell lung cancer

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: 4e geldstroom: commercieel,Astra Zeneca,Hoffmann-La Roche,Novartis

Intervention

Keyword: Circulating tumor DNA, Liquid biopsy, Next-generation sequencing, Non-small cell lung cancer

Outcome measures

Primary outcome

The primary aim of this study is to implement the ctDNA analysis to identify actionable targets in lung tumors.

We envision this study will create awareness in regional hospitals with this novel test method.

Secondary outcome

1. Percentage of patients identified as having an activating and targetable genetic alteration as determined by tissue and liquid biopsies with an intra-individual comparison of the presence of driver mutations detected in tissue and liquid biopsies.

2. To get insight in the time it takes from diangosis to start of targeted treatment.

3. The percentage of patient with inadequate tissue for analysis where ctDNA may be an alternative.

4. Exploring cost- effectiveness

Study description

Background summary

Lung cancer is the second most common cancer and the leading cause of cancer deaths for men and women, In 2019, 9.843 patients were diagnosed with non-small cell lung cancer (NSCLC) in the Netherlands. Despite recent advances made in diagnosis and treatment strategies, NSCLC prognosis remains poor, with a 5-yr overall survival of 15%. In recent years, new methods have been developed for high-throughput molecular analysis of tumours and have provided markers as powerful tools for the development of innovative diagnostic and therapeutic strategies in cancer. Genomic studies have been pioneering in providing information on lung cancer molecular biology, followed by clear evidence that genetic alterations are driving carcinogenesis. Activating somatic mutations including point substitution, small insertion, and in-frame deletion are major oncogenic drivers in lung cancer.

Study objective

Targeted therapies guided by molecular diagnostics have become a standard treatment of lung cancer. Nowadays, tumour tissue is required to assess the molecular characteristics of the tumour. However, the procedures to obtain tissue are invasive and with a concomitant risk of adverse events. A liquid biopsy, which assess circulating tumor DNA (ctDNA) from peripheral blood, may be an alternative for the majority of NSCLC patients.

Nonetheless, ctDNA analysis is not commonly requested in clinical practice due to limited knowhow, experience, availability or lacking logistics. This study aims to implement ctDNA analysis in daily clinical care by adding the logistics needed for this novel test to the regular clinical practice.

Study design

The LICA study is a multicenter trial in which ctDNA analysis will be performed using prospectively collected plasma samples.
At the moment of diagnosis, a single blood draw of 25mL will be requested. In the majority of patients, a tissue biopsy will also be performed as part of the regular clinical care. When there is a high suspicion for stage III/IV disease based on imaging, the ctDNA from plasma will be analyzed. The interpretation of the ctDNA analysis will be independent of the biopsy results and will be reported to the treating physician at a later stage.

Study burden and risks

A sample of blood will be drawn for molecular profiling purposes. This will be

combined with a scheduled blood drawing if possible.

The burden and risks associated with this study are thought to be in balance with the aim to implement this blood based test in the future to replace invasive tissue obtaining procedures.

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 confirmed or suspected non-small cell lung cancer
- Signed informed consent
- Adult (>= 18 years of age) and mentally competent

Exclusion criteria

• Patients with a benign lesion
• Patients with a metastasis of another primary cancer than lung cancer

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-07-2021
Enrollment:	250
Type:	Actual

Ethics review

Approved WMO Date:	17-05-2021
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	09-06-2021
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	28-06-2021
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Approved WMO Date:	22-12-2021
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL76613.091.21