Comparative analysis of KRAS and EGFR mutation detection in liquid biopsy vs tissue biopsy in patients with NSCLC

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In this study, the agreement between liquid biopsy and tissue biopsy based KRAS/EGFR molecular diagnostics will be determined. Additionally, pairwise comparison of different liquid biopsy based molecular tests will be performed based on several...

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

Summary

ID

NL-OMON48625

Source
ToetsingOnline

Brief title
COMMUNIST

Condition

- Respiratory and mediastinal neoplasms malignant and unspecified

Synonym
lung cancer, Non-small-cell lung carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Jeroen Bosch Ziekenhuis
Source(s) of monetary or material Support: Astra Zeneca,AstraZeneca

Intervention

Keyword: Liquid biopsy, Lung cancer, Mutation detection

Outcome measures

Primary outcome

The agreement between liquid biopsy and tissue biopsy based KRAS/EGFR molecular diagnostics that will be determined using Contigency table analysis and comparison of parameters such as specificity, sensitivity, positive and negative predictive values and Cohen*s kappa coefficient.

Secondary outcome

Not applicable.

Study description

Background summary

Routine molecular diagnostics on lung tumors is performed on a biopsy or after resection of the tumor. However, lung tumor biopsy or obtaining representative cytological material is regularly not successful/possible.
Currently, great progress is being made in the field of liquid biopsy where molecular diagnostics is performed on blood and/or urine of the patient involved. Liquid biopsy based molecular diagnostics could be a possible alternative for or be complementary to mutational analysis on a tissue biopsy. Moreover, a liquid biopsy is less invasive in comparison to a tissue biopsy.

Study objective

In this study, the agreement between liquid biopsy and tissue biopsy based KRAS/EGFR molecular diagnostics will be determined. Additionally, pairwise comparison of different liquid biopsy based molecular tests will be performed based on several parameters such as sensitivity and specificity.

Study design

Observational/implementation study based on comparison of routine tissue biopsy

based KRAS/EGFR diagnostics with liquid biopsy based KRAS/EGFR diagnostics.

Study burden and risks

Not applicable.

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 NSCLC (initial diagnosis and progressive disease) that are eligible for KRAS/EGFR mutation analysis on tissue biopsy as performed for standard of care.

Exclusion criteria

Patients with NSCLC where tissue biopsy was not successful.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	21-06-2019
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO Date:	18-03-2019
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	08-05-2019
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	03-07-2019
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO	

Date:	09-10-2019
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	15-01-2020
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

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	NL66646.028.18