proSpecTive sAmpling in dRiver muTation pulmonary oncology patients on Tyrosine Kinase Inhibitors

Published: 15-12-2016
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To collect repeated samples of blood from patients (starting) on TKI, for liquid mutation testing to assess the clinical relevant cutoff value, and pharmacokinetic analysis.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Respiratory tract neoplasms
Study type	Observational invasive

Summary

ID

NL-OMON55730

Source
ToetsingOnline

Brief title
START-TKI

Condition

- Respiratory tract neoplasms

Synonym
lung cancer, non-small cell lung cancer

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: mutation, non-small cell lung cancer, targeted therapy

Outcome measures

Primary outcome

(Resistance) mutation plasma levels, pharmacokinetics of TKI (through levels)

during treatment and at progression.

Secondary outcome

Primary mutation levels, time to progression, correlation to (re)biopsy

specimen results performed for standard-of-care. Furthermore TKI, smoking

status, BMI.

Study description

Background summary

In pulmonary oncology patients with oncogenic driver mutations, TKI are used as targeted therapy, but eventually acquired resistance will take place. Standard of care is to use invasive rebiopsy to diagnose resistance mechanisms, while new methods of testing on circulating tumor material could detect the mutations of interest in plasma. Possibly this means that detection can take place even before clinical progression is seen, without need of an invasive procedure. Pharmacokinetic differences may influence the development of acquired resistance.

Study objective

To collect repeated samples of blood from patients (starting) on TKI, for liquid mutation testing to assess the clinical relevant cutoff value, and pharmacokinetic analysis.

Study design

Observational study with extra blood sampling at already planned moments of blood withdrawal.

Study burden and risks

The extra risk of taking three additional tubes during blood withdrawal is regarded negligible.

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

- Age >= 18 years
- Able to understand the written informed and able to give informed consent
- Locally advanced or metastatic lung cancer with oncogenic driver mutation
- Treatment with TKI according to standard of care

Exclusion criteria

• Unable to draw blood for study purposes

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):	02-03-2017
Enrollment:	1300
Type:	Actual

Ethics review

Approved WMO Date:	15-12-2016
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	09-02-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	20-12-2018
Application type:	Amendment

Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	22-04-2021
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	17-03-2022
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL58664.078.16