Quality Assessment of New Liquid Biopsy Techniques

Published: 21-01-2021
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The main objective of this study is to perform a quality assessment on several new techniques, used in the laboratory of Translational Cancer Genomics and Proteomics

Ethical review	Approved WMO
Status	Pending
Health condition type	Miscellaneous and site unspecified neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON49338

Source
ToetsingOnline

Brief title
EQA of liquid biopsy techniques

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified

Synonym
Cancer, neoplasm

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: Interlaboratory variation, Liquid biopsies, Quality assessment

Outcome measures

Primary outcome

The primary endpoint of this study is to assess quality parameters (intra- and interlaboratory variation, time-to-processing influence, transport influence) of emerging liquid biopsy techniques.

Secondary outcome

Not applicable

Study description

Background summary

Different liquid biopsy assays are already established in oncology research and clinical settings, like circulating tumor DNA assays and quantification of circulating tumor cells using the FDA-approved CellSearch® system. As we move towards the future, liquid biopsies can help us gain insight in tumor evolution and clonal expansion and ultimately be used to choose the best personalized treatment for the individual patients. To reach that aim, emerging techniques have to be of solid quality. The influence of technical aspects on emerging techniques are not yet fully clear, like inter- and intralaboratory differences and the influence of time-to-analysis.

Study objective

The main objective of this study is to perform a quality assessment on several new techniques, used in the laboratory of Translational Cancer Genomics and Proteomics

Study design

Observational study

Study burden and risks

Risk and burden of participating in this study are negligible. Subjects will undergo no extra interventions, since the blood draw is during a regular visit. The treating physician will assess if the subject is fit enough to donate this amount of blood.

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

1. Metastatic cancer
2. Fit enough to deliver a maximum of 120 mL of peripheral blood, assessed by treating physician
3. Written informed consent

Exclusion criteria

None specified

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2020
Enrollment:	30
Type:	Anticipated

Ethics review

Approved WMO

Date:	21-01-2021
Application type:	First submission
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	NL75196.078.20