

Liquid biopsy in mamma carcinoma

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- special attention for the development and harmonization of the pre-analysis of liquid biopsy, for blood as well as urine, and next to this for ctDNA- special attention for the detection of PIK3CA mutations in blood and urine Simultaneously also the...

Ethical review	Approved WMO
Status	Pending
Health condition type	Breast neoplasms malignant and unspecified (incl nipple)
Study type	Observational invasive

Summary

ID

NL-OMON51488

Source

ToetsingOnline

Brief title

LiBiMa

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym

mamma carcinoma, metastasized triple negative mammacarcinoma

Research involving

Human

Sponsors and support

Primary sponsor: Zuyderland Medisch Centrum

Source(s) of monetary or material Support: bedrijf (Farmaceutisch), Novartis

Intervention

Keyword: blood, circulating DNA, mamma carcinoma, tumor heterogeneity

Outcome measures

Primary outcome

- relation between the absence/presence of specific PIK3CA mutations in blood vs primary tumor

Secondary outcome

- relation between the absence/presence of specific PIK3CA mutations in urine vs peripheral blood

Study description

Background summary

- detection of specific mutations in circulating tumor DNA in blood or urine
- in use for a personalised medicine of the patient: tailor-made treatment of the patient with the use of presence/absence of specific mutations as guidance

Study objective

- special attention for the development and harmonization of the pre-analysis of liquid biopsy, for blood as well as urine, and next to this for ctDNA
- special attention for the detection of PIK3CA mutations in blood and urine

Simultaneously also the development of a protocol for its detection in tissue

Study design

Pre-analysis Isolation of cfDNA from blood and urine

- which type of matrix (blood, urine, saliva)
- which type of collection tube
- use of additive
- transport conditions primary sample
- storage conditions primary sample
- possible time till isolation
- centrifugation protocol
- storage conditions isolated ctDNA

Development molecular panel

- special attention to PIK3CA mutations (detection in tissue, blood and urine)

Study burden and risks

Not applicable

Contacts

Public

Zuyderland Medisch Centrum

dr. H. van der Hoffplein 1, Sittard-Geleen 1

Sittard-Geleen 6162 BG

NL

Scientific

Zuyderland Medisch Centrum

dr. H. van der Hoffplein 1, Sittard-Geleen 1

Sittard-Geleen 6162 BG

NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (16-17 years)

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- patients with a metastasized mammacarcinoma

Exclusion criteria

- no other malignancies
- no biopsies of the primary tumor
- patients younger than 16 years
- no informed consent

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): 15-12-2022

Enrollment: 100

Type: Anticipated

Ethics review

Approved WMO

Date: 07-02-2023

Application type: First submission

Review commission: METC Z: Zuyderland-Zuyd (Heerlen)

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	NL82677.096.22