Increasing the CTC detection sensitivity through FETCH technology

Published: 02-10-2023
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Compare the CTC recovery of the CellSearch system for CTC detection to a newly developed method for CTC detection.

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

Summary

ID

NL-OMON53301

Source
ToetsingOnline

Brief title
FETCH-CTC

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
Prostate cancer - Breast cancer

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Twente
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cancer, CTC, Liquid biopsy, Sensitivity

Outcome measures

Primary outcome

The number of CTC found for each of the two methods.

Secondary outcome

Number of healthy cells co-captured using the two tested methods.

Study description

Background summary

In many cancer types, the number of circulating tumour cells (CTC) detected by the FDA-cleared CellSearch system in a 7,5mL blood sample is predictive of disease prognosis, treatment outcome and relapse prediction. Additionally the makeup of these cells can be used to signal tumour changes such as those underlying resistance. However, due to their low frequency, the detected number of CTC currently found in standard blood tube using the CellSearch system is often 0. In light of recent findings on the low expression of the antigen used by the CellSearch system for CTC capture, we believe that using a more sensitive method of CTC detection makes it possible to detect and characterize CTC in a larger percentage of cancer patients.

Study objective

Compare the CTC recovery of the CellSearch system for CTC detection to a newly developed method for CTC detection.

Study design

The study is a performance study where two blood tubes from each patient will be processed simultaneously using two methods and the detected numbers of CTC will be compared.

Study burden and risks

The participants will have two additional tubes of blood taken during a regular visit. No additional venipuncture will be performed.

This will prolong the existing blood collection procedure by approximately 1-2

minutes.

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

Diagnosed metastatic breast cancer OR metastatic castration resistant prostate cancer
A planned blood collection
At least 18 years of age

Exclusion criteria

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):	01-09-2023
Enrollment:	40
Type:	Anticipated

Medical products/devices used

Generic name:	FETCH - CTC -detection
Registration:	No

Ethics review

Approved WMO Date:	02-10-2023
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	04-03-2024
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	NL83876.000.23