Detection and characterization of circulating tumor cells in cancer patients

Published: 30-03-2010
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Improving isolation and characterization technologies for CTC.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Miscellaneous and site unspecified neoplasms benign
Study type	Observational invasive

Summary

ID

NL-OMON34754

Source
ToetsingOnline

Brief title
CTC phenotyping

Condition

- Miscellaneous and site unspecified neoplasms benign

Synonym
Cancer spread, Metastasis

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Characterization, Circulating tumor cells

Outcome measures

Primary outcome

The blood specimens will be used to isolate, enumerate, and characterize the circulating cells. Fluorescently labeled antibodies for tumor specific and/or tissue specific markers among others will be used to identify, count and characterize the circulating cells. The blood samples and isolated cells may also be used for the detection of altered, over-, or under-produced cancer-related molecules, including gene expression studies of genes that may be related to the response of cancer cells to therapeutics. Genetic studies will be done to determine their importance in response to therapies, not to test for genetic sequences for the purpose of identifying inherited genetic disorders. Remaining blood samples and their components may be saved for possible use in future investigations related to cancer research, including detection of altered, over-, or under-produced cancer-related molecules.

Secondary outcome

Not applicable

Study description

Background summary

The presence of circulating tumor cells (CTCs) in patients with metastatic breast, colorectal and prostate cancer is strongly associated with a short progression free and overall survival. Failure to eliminate CTCs after the first cycle(s) of therapy is indicative for a futile therapy. Various studies are ongoing how to best use CTC in the management of the disease of patients with metastatic carcinomas. At Twente University technology is being developed to further improve the identification and characterization of Circulating Tumor

Cells and blood of cancer patients is needed for these studies.

Study objective

Improving isolation and characterization technologies for CTC.

Study design

This study will be an Institutional Review Board (IRB) approved single-site, single blind case study. A maximum of 40mL (approximately 8 teaspoons) of whole blood per draw will be used to determine the ability of various in-vitro tests to isolate circulating cells and/or their components, to compare circulating cell enumeration by fluorescent image analysis and/or flow cytometric methods, to evaluate the stability of the circulating cells and integrity of genetic material (i.e. RNA and DNA), and to characterize the circulating cells and/or cellular components isolated from advanced cancer patients using protein RNA and or DNA analyses.

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

Minimal age 18 years
Diagnosis Stage IV solid carcinoma
Minimum of seven days since last therapie (exept daily administration therapies)
Signed informed consent form

Exclusion criteria

Under the age of 18 years
Early stage disease
Patients unwilling/unable to give consent

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-03-2011
Enrollment:	150

Type:	Actual

Ethics review

Approved WMO Date:	30-03-2010
Application type:	First submission
Review commission:	METC Twente (Enschede)
Approved WMO Date:	20-03-2012
Application type:	Amendment
Review commission:	METC Twente (Enschede)

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	NL30621.044.09