ENUMERATION AND CHARACTERISATION OF CIRCULATING TUMOR CELLS (CTC) IN PATIENTS WITH SOLID MALIGNANCIES

Published: 17-10-2007
Last updated: 14-05-2024

To enumerate and characterize CTC in patients with solid malignancies before and, if applicable, after initiation of systemic treatment in order to improve the insight in the pathogenesis of metastases, and in mechanisms conferring resistance...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Metastases
Study type	Observational invasive

Summary

ID

NL-OMON30560

Source
ToetsingOnline

Brief title
Circulating Tumor Cells, solid malignancies

Condition

- Metastases

Synonym
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: circulating, solid malignancies, tumor cells

Outcome measures

Primary outcome

To enumarate and characterize CTC's.

Secondary outcome

nvt

Study description

Background summary

There is a growing need to characterize the prognostic and predictive factors of cancer patients better. In various tumor types a number of these factors are indentified in the primary tumor (for example through a genetic profile). Metastatic lesions are the primary cause of death in cancer patients. It is to be expected that the characteristics of CTC's, who eventually will be formed to metastases, are better predictable for the outcome of the patient than characteristics found in the primary tumor. In this study in patients with various malignancies CTC's will be enumareted and isolated for possible prognostic and predictive factors. Next to CTC enumeration comparing characteristics of CTC and the primary tumor will improve the insight in the pathogenesis of metastases and the insight in mechanisms conferring resistance against systemic treatments.

Study objective

To enumerate and characterize CTC in patients with solid malignancies before and, if applicable, after initiation of systemic treatment in order to improve the insight in the pathogenesis of metastases, and in mechanisms conferring resistance against systemic treatments and to establish prognostic and predictive models for clinical outcome.

Study design

In participating patients, a 30 ml. blood sample will be drawn. In patients who will be treated with systemic therapy another 20 ml. blood sample will be drawn 3-4 weeks after start of the therapy. CTC will be enumerated and isolated.

Characteristics of the CTC's will be compared to amd asessed tp the available characteristics of the primary tumor and clinical outcome.

Study burden and risks

None, blood samples will be drawn during regular visits for a blood check up of the patient during treatment of his/her disease. There will not be taken extra blood samples.

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

- Patients suffering from one of the below mentioned solid malignancies. For patients with

metastatic disease, only those who will be treated with first line systemic treatment will be recruited.
o metastatic breast cancer (number 100-150)
o localized breast cancer (number 100-150)
o metastatic colorectal cancer (number 100-150)
o localized colorectal cancer (number 100-150)
o metastatic prostate cancer (number 100-150)
o metastatic other tumor types such as testicular cancer, soft tissue sarcoma, renal cell carcinoma, lung carcinoma (in total maximum number 100-150);- Absence of any psychological, familial, sociological or geographical condition potentially hampering compliance with the study protocol and follow-up schedule; those conditions should be assessed with the patient before registration in the trial.;- Before patient randomization, written informed consent must be given and documented to ICH/EU GCP, and national/local regulatory requirements and the local rules followed in the institution

Exclusion criteria

Geen

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-01-2008
Enrollment:	900
Type:	Actual

Ethics review

Approved WMO Date:	17-10-2007
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	NL12101.078.06