Development of an assay for detection of Circulating Endothelial Cell (CEC) and Circulating Endothelial Progenitor cell (CEP) by fluorescence-activated cell sorting (FACS) in cancer patients and healthy individuals.

Published: 08-07-2014
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Produce a reproducible method for enumeration of CECs and CEPs in peripheral blood in order to further study the usefulness of CECs and CEPs as a biomarker in LDM therapy.

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

Summary

ID

NL-OMON40594

Source
ToetsingOnline

Brief title
Development and validation of the CEC/CEP FACS assay

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified

Synonym
Cancer, malignancy

Research involving

Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cancer patients, circulating endothelial cells, fluorescence activated cell sorting (FACS), Healthy individuals

Outcome measures

Primary outcome

A reproducible method for enumeration of CECs and CEPs in peripheral blood

using FACS

Secondary outcome

Gain further insight in the origin of CECs and CEPs.

Study description

Background summary

CEC and CEPs play een important roll in angiogenisis both in health tissiue and in tumor tissue. In patients with cancer these cells are up regulated. Higher numbers of CEC/CEPs negatively correlate to survival of patients after chirugery and also for chemotherapy.

In traditionally administered chemotherapy a burst release of CECs and CEPs is seen shortly after therapy. This burst release is related to a pro-angiogenic state in which the vasculature of the tumor is restored resulting in tumor growth and therefore limiting efficacy of therapy.

In metronomic therapy traditional chemotherapeutic agents are given in very low doses. These low doses are toxic to CEC and CEPs and therefore inhibit tumor growth, since the lack the ability to restore the tumor vasculature will result in ischemia and will thereby halt tumor growth.

Because of the reasons mentioned above we see additional value for CEC/CEPs as

a diagnostic marker. With the development of this assay we hope to be able to better predict efficacy of metronomic therapy in cancer patients.

Study objective

Produce a reproducible method for enumeration of CECs and CEPs in peripheral blood in order to further study the usefulness of CECs and CEPs as a biomarker in LDM therapy.

Study design

Both healthy individuals and cancer patients will be asked to donate blood for the further development and validation of the CEC/CEP FACS assay.
Only blood collection will be performed. Inclusion will be performed only if samples of patients/controls are needed.

Study burden and risks

The burden for the patients will be limited, extra blood will be collected during a regular visit. Up to 24ml of blood will be drawn per time point. Patients will be asked to donate blood up to 5 times.

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

bInclusion criteria cancer patients:
1. Patients with histological or cytological proof of metastatic cancer.
2. Age * 18 years
3. Able and willing to give written informed consent
4. Able and willing to undergo blood sampling ;Inclusion criteria healthy volunteers:
1. Age * 18 years
2. Able and willing to give written informed consent
3. Able and willing to undergo blood sampling

Exclusion criteria

Exclusion criteria cancer patients:
1. Patients with known alcoholism, drug addiction, psychotic disorders in the history and/or other reasons, for which they are not amenable for adequate follow up.
2. Uncontrolled infectious disease or known HIV-1 or HIV-2 type patients ;Exclusion criteria healthy volunteers:
1. Patients with known alcoholism, drug addiction, psychotic disorders in the history and/or other reasons, for which they are not amenable for adequate follow up.
2. Uncontrolled infectious disease or known HIV-1 or HIV-2 type patients
3. Prior history of malignancy, renal disease, cardiovascular disease.

Study design

Design

Study type: Observational invasive
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	31-03-2015
Enrollment:	70
Type:	Actual

Ethics review

Approved WMO

Date:	08-07-2014
Application type:	First submission
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)

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	NL46654.031.14