Measuring the endothelial glycocalyx in cancer patients and determining the effect of chemotherapy

Published: 09-02-2009
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To investigate the state of the endothelial glycocalyx in cancer patients and determine the effect of chemotherapy on this layer.

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

Summary

ID

NL-OMON33421

Source
ToetsingOnline

Brief title
Glycocalyx in cancer

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified

Synonym
cancer, neoplasms

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: gastro-intestinal cancer (gastric, glycocalyx, multiple myeloma, oesophageal and colon cancer)

Outcome measures

Primary outcome

Assessment of the glycocalyx in cancer patients and comparison to healthy

controls by

- Orthogonal Polarisation Spectroscopy (OPS)

- Blood/urine parameters

Secondary outcome

The influence of chemotherapy on the primary parameters.

Correlation of the glycocalyx state to the activation of the coagulation and

clinical data after 3 months of follow-up.

Study description

Background summary

Functions of the endothelial glycocalyx are the preservation of the endothelial barrier and to prevent adhesion of cells to the endothelial wall. In cancer, elevated levels of heparanase and hyaluronidase are described, which are enzymes extensively described in local tumour invasiveness. However, these enzymes are also known for their glycocalyx degrading effects. The glycocalyx has not been described in cancer patients yet. A damaged glycocalyx might allow adhesion of cancer cells to the blood vessel wall and these cells can more easily cross the vessel wall. This way, metastasis would be promoted. Also, the hypercoagulant state in cancer might be in part due to a perturbation of the glycocalyx. Chemotherapy is known to induce endothelial damage, probably also to the glycocalyx, which may explain the hypercoagulant state caused by chemotherapy. Alternatively, restoration of the glycocalyx may be one of the anti-tumour effects of chemotherapy, possibly via inhibition of the production of the glycocalyx degrading enzymes.

Study objective

To investigate the state of the endothelial glycocalyx in cancer patients and determine the effect of chemotherapy on this layer.

Study design

Observational case-control study

Study burden and risks

The patients will visit the hospital on three occasions, of which two in a semi fasting state (3 hours no food-intake). On the first occasion, screening is done and informed consent is taken. During the first research visit, before chemotherapeutic therapy has been initiated, the patients will be asked to fill out a questionnaire and they will undergo OPS measurement (non-invasive imaging of the sublingual microcirculation) and venapuncture (blood withdrawal 30 ml). Also, they will be asked to hand over one portion of urine.
During the second visit, after the start of chemotherapy, the same procedure will take place.
After three months of follow-up, information about the progression of the disease will be obtained (no extra visit needed).

Visits will be planned simultaneously with visits for regular patient care.
Also, blood withdrawings will be planned simultaneously with blood withdrawings for regular patient care as much as possible.

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

Men and postmenopauzal women
Aged over 18 years
Informed consent
Metastasized gastric or oesophageal or colon cancer, not yet started with chemotherapy
Multiple myeloma;Healthy volunteers: healthy men or post-menopauzal women, aged over 18, informed consent

Exclusion criteria

Diabetes mellitus
Cardiovascular disease
Medication used for the above mentioned diseases
Pre-menopauzal women

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-01-2009
Enrollment:	75
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL26451.018.08