The effect of chemotherapy on procoagulant microparticles in patients with cancer

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Primary objective: To monitor levels of microparticles in response to a gift of chemotherapy on short term and in response to multiple gifts of chemotherapy. Secondary objective 1: To compare microparticle levels measured in blood acquired via a...

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

Summary

ID

NL-OMON33135

Source
ToetsingOnline

Brief title
Chemotherapy and microparticles

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: cancer, chemotherapy, microparticles

Outcome measures

Primary outcome

Levels and activity of microparticles in respond to a gift of chemotherapy

Secondary outcome

1. Difference in activity and levels of microparticles between blood withdrawal

via vene puncture and venflon

2. Correlation between microparticle levels and activity and markers of

coagulation activation.

Study description

Background summary

Chemotherapy is one of the most important factors adding to the risk of thrombosis in cancer patients. The risk of thrombosis varies among different chemotherapeutic regimes. The pathogenesis of chemotherapy-associated hypercoagulability is not completely understood, but may include cytotoxicity on both malignant and non-malignant cells leading to increased apoptosis, interactions with blood cells and vascular toxicity.
Microparticles are thought to contribute to the procoagulant state in cancer patients. Microparticles are small, membrane-bound vesicles that are released from various types of cells. Also cancer cells can release these 200-1500 nm sized membrane fragments. These vesicles bear at least some characteristics of the parent cell and are therefore considered as being active players in processes such as cellular communication, angiogenesis, coagulation and invasiveness. High levels of microparticles have been described in patients with different types of cancer. Significantly higher levels of microparticles have been found in cancer patients with venous thrombosis compared with cancer patients without thrombosis.
Reports on the influence of chemotherapy on microparticle levels are scarce. Microparticles are not only procoagulant in cancer, but also play an important role in tumour progression. Reports on the rol of microparticle release in resistance of the tumor to chemotherapy are scarce but interesting. Two

research groups reported the existence of tumour cell derived microparticles containing chemotherapeutic, which suggests that the shedding of microparticles, plays a role in the resistance of cancer cells to chemotherapy. However, no in vivo careful monitoring of microparticle levels in respons to chemotherapy has been done. Therefore, the aim of the present study is to evaluate the effect of chemotherapy on microparticle levels and activity in patients with cancer and observe changes in microparticle levels and activity after a gift of chemotherapeutic.

A second question which will be addressed by this study is whether microparticle levels measured after blood withdrawal via vein puncture are significantly different from microparticle levels measured after blood withdrawal via a peripheral venous catheter. Blood withdrawal via a venous catheter, which is already present because chemotherapy will be administered via this catheter, is more convenient for patients compared to an additional vein puncture. Therefore, when we find in this study that both methods are equal to each other in measured microparticle levels, this would prevent unnecessary blood withdrawals for patients in future studies.

Study objective

Primary objective: To monitor levels of microparticles in response to a gift of chemotherapy on short term and in response to multiple gifts of chemotherapy.
Secondary objective 1: To compare microparticle levels measured in blood acquired via a vein puncture with microparticles levels in blood acquired via a peripheral venous catheter.
Secondary objective 2: To determine the correlation between levels of microparticles and markers of coagulation activation.

Study design

We will collect blood samples from patients with different types of cancer, treated with specific chemotherapy regimes. Participation consists of donations of serial blood samples. Each donation 5 tubes containing 2,5 ml of citrated blood will be withdrawn. Patients will not be asked to attend the hospital for research purposes only.
Microparticles will be measured via flow cytometry, Xa Clotting Test and the Fibrin Generation Test. Also, markers of blood coagulation will be determined.

Study burden and risks

No benefits can be expected for individual patients who participate in this study. However, more information on this subject can help in the identification of patients with cancer receiving chemotherapy with the highest risk of venous thrombosis. Extra knowledge on the effects and side-effects of chemotherapy might in the future lead to a greater understanding of chemo-resistance and

factors who determine whether or not patients will respond to chemotherapy. If knowledge on this subject becomes incorporated into patient care, it will be in the same group of patients who participate in the present study.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
1100 DD
Nederland
Scientific
Academisch Medisch Centrum

Meibergdreef 9
1100 DD
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Signed informed consent
Aged over 18
Capable of making health related decisions
Cancer patients, of certain types and treated with specific regimes of chemotherapy

Exclusion criteria

Deep venous thrombosis
Pulmonary Embolism
Anticoagulant use

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):	20-04-2009
Enrollment:	90
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	NL27556.018.09