The role of microparticles bearing active tissue factor in cancer and thrombosis: "The Bouillaud Study"

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Primary objectivesIn all patients included in the studyTo asses whether:- MP-TF activity and MP phenotype is associated with specific types of malignancy.- MP-TF activity and MP phenotype predicts for development of thrombosis.- MP-TF activity and...

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

Summary

ID

NL-OMON32659

Source
ToetsingOnline

Brief title
Microparticles and tissue factor in cancer and thrombosis

Condition

- Miscellaneous and site unspecified neoplasms benign

Synonym
cancer, malignancy

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: KWF/NKB

Intervention

Keyword: cancer, microparticles (MP), thrombosis, tissue factor (TF)

Outcome measures

Primary outcome

Study variables; MP-TF activity, MP phenotypes, cytokines, FV Leiden, FII mutations, sTF and sP-selectin.

We will compare the results of the study variables (see above) between the different cancer types and between patients and healthy volunteers.
The level of MP-TF activity and MP phenotypes will also be compared with patients who did and did not developed thrombosis, patients who did and did not undergo a change in the stage of their disease and survival between the different groups of patients.

Secondary outcome

MP-TF activity, MP-phenotypes, FV Leiden and FII mutations in the controle group.

Study description

Background summary

The role of microparticles bearing active tissue factor in cancer and thrombosis: "The Bouillaud study"

The incidence of cancer is growing with increased ageing of people and cancer is now the leading cause of death in the West European countries and the US. Hypercoagulability seems to contribute to the two most frequent causes of death in cancer patients, namely metastases and venous thrombosis. The poor prognosis of cancer patients who develop thrombosis forms a challenge to clinicians to

select cancer patients at highest risk for development of thrombosis and to develop effective prophylactic strategies to prevent thrombosis and hopefully also improve survival.

Although the relationship between cancer and thrombosis has been known for more than a century, the mechanism by which tumour predispose to thrombosis has not been elucidated. The activation of blood coagulation in patients with cancer may well have several causes. Prothrombotic mechanisms may be related to the host's response to cancer and other factors to procoagulant properties of the cancer cells themselves.

The aim of this prospective cohort study is to investigate the role of MP-TF activity and MP phenotypes in specific types of malignancies and to assess if it are predictive markers for the development of thrombosis, progression of the malignant disease and survival.

Study objective

Primary objectives
In all patients included in the study
To asses whether:
- MP-TF activity and MP phenotype is associated with specific types of malignancy.
- MP-TF activity and MP phenotype predicts for development of thrombosis.
- MP-TF activity and MP phenotype predicts for an unfavorable course of the disease (progression).

In patients who develop thrombosis or embolism
To assess whether:
- MP-TF activity is elevated at the time of clinically manifest and radiologically confirmed venous thromboembolism and whether MP-TF activity levels change after a period of 1-2 months of effective anticoagulation.

In patients who undergo a change in the stage of their disease
To assess whether:
- MP-TF activity is elevated at the time of a significant change in stage of the disease (progression).

Secundary objectives
To investigate:
- MP-TF activity and phenotype in healthy subjects to assess the levels an standard deviation in healthy controls.
- Other possibly relevant factors such as circulating levels of P-selectin and tissue factor as well as Factor V Leiden and prothrombin mutation, the two major risk factors for development of thrombosis in the normal population.

Study design

Prospective cohort study

Study burden and risks

Patients:
- One questionaire at the start of the study.
- Patients will be contacted every 3 months by the dedicated research nurses to get information about the clinical course of their disease and with regard to occurrence of thrombosis.

Blood collection (30ml blood) at the following moments;
1) at start from the study (all patients)
2) in case of thrombosis (within 24hr or max. 48h after diagnoses) preferably before the start of anticoagulation therapy.
3) 1-2 months after the occurence of thrombosis.
4) at the time of a change in the stage of the disease (progression) and in any case before the start of any systemic anti-cancer treatment.

The total times of blood collection will thus differ per patient. It will depent of the times and onset of each moment.
We will try to make it as less invasive as possible for the patient by planning the blood collection at the time of routine laboratory controls or when ít is suitable for the patient .

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 diagnosed with carcinomas(epithelial tumors) of the gastrointestinal tract including colorectal, pancreatic,stomach and bowel. Patients with cancer of the genito-urinary tract (i.e prostate and renal tumours). Also patients with adeno-and squamous carcinomas of the lung, cancer of the ovaries and hematological malignancies.

Exclusion criteria

pregnant women
recent immobilization
systemic (chemo)therapy for metastatic disease

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2008
Enrollment:	700
Type:	Anticipated

Ethics review

Approved WMO Date:	17-12-2008
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL24355.058.08