Coagulation in Colorectal cancer.

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Cancer patients who develop thrombosis have a worse prognosis than cancer patinets without thrombosis. There is evidence that activation of the coagulation cascade increases tumor growth and angiogenesis. Therefore the objective is to find a marker...

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON22944

Bron
NTR

Verkorte titel
the CoCo study

Aandoening

colorectal cancer, colorectaal carcinoom, coagulation, stolling, angiogenesis, angiogenese, thrombosis, trombose, prognosis, prognose

Ondersteuning

Primaire sponsor: MUMC+
Overige ondersteuning: MUMC+

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Primary Objective: the association between tissue factor positive microparticles level in colorectal cancer patients and time to progressive disease.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:
Cancer patients who develop a venous thrombotic event have a worse prognosis compared to patients without thrombosis. There is evidence that activation of the coagulation cascade increases tumor growth and angiogenesis.

Objective:
To find a marker linked to angiogenesis and coagulation to predict prognosis in cancer patients.

Study design:
Multicenter prospective cohort study.

Study population:
colorectal cancer patients, all disease stages.

Main study parameters/endpoints:

Primary Objective: the association between tissue factor positive microparticles level in colorectal cancer patients and time to progressive disease.

Secondary Objectives:

1. The association between the other chosen markers (thrombomodulin, von Willebrand factor, VEGF, Tissue factor, cancer procoagulant, thrombin generation, PAI-1, PAP complex, CRP, d-dimer, P-selectin, thrombospondin-1) and time to progressive disease;

2. The association between the chosen markers and the occurrence of a VTE;

3. The association between the chosen markers and disease stage;

4. The association between the chosen markers and the use of chemotherapy;

5. The association between the chosen markers and the use of bevacizumab.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:
In colorectal cancer patients extra blood will be sampled. In every venous puncture 25 ml extra blood will be sampled. There is no need for extra visits or patient questionnaires. Therefore there is no extra risk expected with a minimum of burden. Also already excised tumor tissue will be examined. Extra blood sampling will occur depending on treatment schedule for a minimum of two times to a maximum of six times.

Doel van het onderzoek

Cancer patients who develop thrombosis have a worse prognosis than cancer patinets without thrombosis. There is evidence that activation of the coagulation cascade increases tumor growth and angiogenesis. Therefore the objective is to find a marker in blood linked to angiogenesis and coagulation to predict the prognosis in cancer patients.

Onderzoeksopzet

Blood will be sampled at specific points in treatment and in case of progressive disease and thrombosis. Patients will be followed two years.

Onderzoeksproduct en/of interventie

N/A, observational study.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients newly diagnosed with colorectal cancer who have not yet been treated;

2. Any disease stage;

3. Age 18 years or older.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Second primary tumor in the past 5 years, except basal cell carcinoma and in situ carcinomas;

2. Not able to give written informed consent.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-10-2009
Aantal proefpersonen:	300
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1672
NTR-old	NTR1773
Ander register	METC MUMC : 09-2-033
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten

N/A