Coagulation in Colorectal cancer.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON22944

Source
NTR

Brief title
the CoCo study

Health condition

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

Sponsors and support

Primary sponsor: MUMC+
Source(s) of monetary or material Support: MUMC+

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

Secondary Objectives:

1. The association between the other chosen markers (thrombomodulin, vWf, tissue factor, cancer procoagulant, thrombin generation, PAP-complex, PAI-1, d-dimer, P-selectin, VEGF, Thrombospondi1, CRP) 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.

Study description

Background summary

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.

Study objective

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.

Study design

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

Intervention

N/A, observational study.

Contacts

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Eligibility criteria

Inclusion criteria

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

2. Any disease stage;

3. Age 18 years or older.

Exclusion criteria

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.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2009
Enrollment:	300

Type: Anticipated

Ethics review

Not applicable
Application type: Not applicable

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
NTR-new	NL1672
NTR-old	NTR1773
Other	METC MUMC : 09-2-033
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A