Coagulation in colorectal cancer

Published: 31-08-2009
Last updated: 06-05-2024

To find procoagulant markers predictive of progression of the underlying malignancy or predictive of the occurrence of a venous thrombotic event.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coagulopathies and bleeding diatheses (excl thrombocytopenic)
Study type	Observational invasive

Summary

ID

NL-OMON33373

Source
ToetsingOnline

Brief title
the CoCo study

Condition

- Coagulopathies and bleeding diatheses (excl thrombocytopenic)
- Gastrointestinal neoplasms malignant and unspecified

Synonym
colorectal cancer, malignancy

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Roche is gevraagd als sponsor, maar heeft nog geen definitief antwoord gegeven. Indien ze sponsor zijn (ivm bevacizumab) zal dit maar voor een klein deel zijn

Intervention

Keyword: biomarkers, cancer, colorectal, thrombosis

Outcome measures

Primary outcome

Primary study endpoint is the association between tissue factor positive microparticles level in colorectal cancer patients and time to progression.

Secondary outcome

The association between other procoagulant markers (thrombomodulin, von Willebrand factor, PAP-complex, PAI-1, P-selectin, thrombospondin 1, tissue factor, cancer procoagulant, VEGF, thrombin generation, d-dimer) and time to progression.

The association between procoagulant markers (tissue factor positive microparticles, thrombomodulin, von Willebrand factor, PAP-complex, PAI-1, P-selectin, thrombospondin 1, tissue factor positive microparticles, tissue factor, cancer procoagulant, VEGF, thrombin generation, d-dimer) and the occurrence of a VTE.

The association between procoagulant markers (tissue factor positive microparticles, thrombomodulin, von Willebrand factor, PAP-complex, PAI-1, P-selectin, thrombospondin 1, tissue factor positive microparticles, tissue factor, cancer procoagulant, VEGF, thrombin generation, d-dimer) and disease stage.

The association between procoagulant markers (tissue factor positive microparticles, thrombomodulin, von Willebrand factor, PAP-complex, PAI-1, P-selectin, thrombospondin 1, tissue factor positive microparticles, tissue

factor, cancer procoagulant, VEGF, thrombin generation, d-dimer) and the use of chemotherapy.

The association between procoagulant markers (tissue factor positive microparticles, thrombomodulin, von Willebrand factor, PAP-complex, PAI-1, P-selectin, thrombospondin 1, tissue factor positive microparticles, tissue factor, cancer procoagulant, VEGF, thrombin generation, d-dimer) and the use of bevacizumab.

Study description

Background summary

There is an increased incidence of thrombosis in cancer patients. Thrombosis leads to an increased morbidity, but can also lead to an increased mortality (fatal pulmonary embolism). Besides the increased mortality due to a fatal pulmonary embolism, cancer patients with thrombosis have a poorer prognosis compared to cancer patients without thrombsis. The activated coagulation cascade in patients with malignancy leads to tumor growth and angiogenesis.

Study objective

To find procoagulant markers predictive of progression of the underlying malignancy or predictive of the occurrence of a venous thrombotic event.

Study design

multicentre prospective cohort study.
In colorectal cancer patients blood will be sampled combined with already planned venous punctures.
Also tumor tissue removed at the planned operation will be examined.

Study burden and risks

There is no increased risk for the patient. There is hardly any burden for the patient since the sampling of blood is already combined with planned venous punctures. Therefore there is no need for extra venous punctures. Th examination of the tumor tissue also does not lead to an increased burden,

since this tissue will be removed in an already planned operation.

Contacts

Public
Selecteer

P. Debeyelaan 25
6229 HX Maastricht
NL
Scientific
Selecteer

P. Debeyelaan 25
6229 HX Maastricht
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

colorectal cancer, any stage, not yet treated before

Exclusion criteria

second primary tumor, except basal cell carcinoma

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2009
Enrollment:	300
Type:	Anticipated

Ethics review

Approved WMO

Date:	31-08-2009
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL27030.068.09
Other	nummer volgt binnen 4 weken op trialregister.nl