Peroperative detection of disseminated tumorcells in blood by patients with colon cancer

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Is is possible to detect tumorcells in blood in patients with colon cancer with RT-q-PCR.

Ethical review Approved WMO

Status Pending

Health condition type Malignant and unspecified neoplasms gastrointestinal NEC

Study type Observational invasive

Summary

ID

NL-OMON29810

Source

ToetsingOnline

Brief title

Disseminated tumorcells in patients with colon cancer

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC
- Gastrointestinal neoplasms malignant and unspecified

Synonym

cancer, metastases

Research involving

Human

Sponsors and support

Primary sponsor: Jeroen Bosch Ziekenhuis

Source(s) of monetary or material Support: ziekenhuis zelf

Intervention

Keyword: colon, detection, disseminated, tumor cells

Outcome measures

Primary outcome

Increase of tumorcells in blood in patients with metastases.

Secondary outcome

none

Study description

Background summary

The incidence of colon tumours has strongly increased for the last few years. About twenty to forty-five percent of the patients who have underwent a curative resection will develop metastases in time. A possible reason is the dissemination of tumor cells. dissemination can occur during the early phase of tumor growth or during surgery(manipulation). The technique of RT-q-PCR could be an attractive method to detect tumorcells in blood.

Study objective

Is is possible to detect tumorcells in blood in patients with colon cancer with RT-q-PCR.

Study design

By ten healthy persons 10 ml of blood will be drawn from the vena cephalica. These persons will form the negative control group. From ten patients with colon cancer with metastases also 10 ml of bloood will be drawn from the vena cephlica. These patients will form the positive control group. If the results are positive the next step will be as follows. By ten patients with colon cancer without metastases blood will be drawn before surgery and during surgery from the vena cephalica, vena portae and vena cava inferior (total 60 ml). The blood will be examined with RT-q-PCR to detect tumorcells.

Study burden and risks

There is a chance of haematoma at the site of punction and a small risk of bleeding from the vene.

Contacts

Public

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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

Inclusion criteria

> 18 years, curative colon cancer

Exclusion criteria

< 18 years, metestases

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): 01-07-2006

Enrollment: 30

Type: Anticipated

Ethics review

Approved WMO

Application type: First submission

Review commission: METC Brabant (Tilburg)

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

ССМО

NL13304.028.06