

Detection of disseminated tumour cells in blood in patients with colon cancer who are operated upon laparoscopically

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Is het mogelijk om te bevestigen de aanwezigheid van disseminerende tumorcellen in het bloed bij patiënten met colonic cancer die laparoscopisch worden geopereerd?

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Observational invasive

Summary

ID

NL-OMON31633

Source

ToetsingOnline

Brief title

detection of tumour cells during laparoscopic colonic surgery

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC
- Gastrointestinal therapeutic procedures

Synonym

colon cancer, colonic carcinoma

Research involving

Human

Sponsors and support

Primary sponsor: Jeroen Bosch Ziekenhuis

Source(s) of monetary or material Support: Commissie wetenschappelijk onderzoek JBZ

Intervention

Keyword: blood, colon cancer, disseminated tumour cells, laparoscopy

Outcome measures

Primary outcome

The presence of disseminated tumor cells in blood, which means an elevated signal of CK20 and CEA in the RT-qPCR.

Secondary outcome

none

Study description

Background summary

Colon cancer is one of the most common cancer in the Netherlands. The most important predictor of survival is the presence of lymph node or distant metastasis.

Still, in 30-45% of the patients with curatively resected colon cancer with no lymph node involvement, local regional recurrence or distant metastasis will occur.

A plausible explanation could be the dissemination of tumor cells via blood or lymphatic system.

A method for detection of disseminated tumor cells is RT-qPCR. With RT-qPCR it is possible to detect specific genetic markers on tumor cells. In colon carcinoma, the expression of the genetic markers CK-20 and CEA are often elevated.

A technique which is used more and more in colonic surgery is the laparoscopy. The main difference between the conventional operation and the laparoscopic is, besides its minimal invasive character, the approach to the tumour. During laparoscopy, first the vessels are ligated, after which the tumour will be surgically removed. In the conventional operation first the tumour is approached and resected, after which the vessels are ligated.

Because patients with colonic cancer are more often operated upon laparoscopically, it is usefull to know if disseminated tumor cells can be determined in peripheral blood.

Study objective

Is het mogelijk om de aanwezigheid van disseminerde tumorcellen in het bloed te bevestigen bij patiënten met colorectaal kanker die worden geopereerd met laparoscopie?

Study design

In tien patiënten met een colorectaal carcinoom die een curatieve laparoscopische chirurgische resectie zullen ondergaan, worden bloedproeven genomen uit de cephalische ader en de inferieure vena cava. In totaal wordt 20 ml bloed (10 ml van elk punctiepunt) genomen zodra deze twee plaatsen geïncubeerd zijn. Na de resectie van de tumor wordt nogmaals 20 ml bloed genomen uit dezelfde plaatsen.

Het bloed wordt naar het laboratorium afgegeven voor rt-PCR om de expressie van CK20 en CEA te bevestigen.

Study burden and risks

De kans op bloeding is gelijk bij laparoscopische en conventionele chirurgie. De kans op infectie is minimaal vanwege de sterile omstandigheden in de operatiekamer en is niet groter dan bij andere vormen van chirurgie.

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

proven colonic carcinoma

no pre-operative suspicion of distant metastasis

older than 18 years

written informed consent given

laparoscopic operation

Exclusion criteria

distant metastasis

irresectable tumour

Conversion to open procedure

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 01-01-2008

Enrollment: 10

Type: Actual

Ethics review

Approved WMO

Date: 15-10-2008

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

CCMO

ID

NL20637.028.07