

# 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 de aanwezigheid van disseminerde tumorcellen in het bloed te bepalen bij patiënten met colonic cancer die laparoscopisch zijn geopereerd?

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Malignant and unspecified neoplasms gastrointestinal NEC
<b>Study type</b>	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 disseminerende 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 ondergaan, worden bloedproeven genomen uit de cephalische ader en de inferieure vena cava. In totaal wordt 20 ml bloed (10 ml van elke punctieplaats) genomen zodra deze twee plaatsen geïncubeerd kunnen worden. Na 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 door de sterile omstandigheden in de operatiekamer en niet groter dan bij andere vormen van chirurgie.

## Contacts

### Public

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### Scientific

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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	ID
CCMO	NL20637.028.07