

# Relevance of circulating tumour cells in patients undergoing laparoscopic colon resection versus open resection: a randomised trial

<b>Submission date</b> 20/12/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 20/12/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 18/11/2008	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

NTR277

# Study information

## Scientific Title

## Acronym

CTC-trial

## Study objectives

We hypothesise that free circulating tumour cells can be detected during surgery in patients with colorectal cancer. Since minimal invasive surgery causes less trauma and tumour manipulations we hypothesise that the amount of free circulating tumour cells is less compared to the level detected during open surgery in comparable patient groups. Minimal invasive surgery causes less severe impairment of the immune system compared to open surgery. Since the surgical trauma might enhance tumour shedding and compromises immune function, the minimally invasive surgery for colorectal cancer might both lower the risk of tumour shedding and result in less compromised immune down-regulation resulting in better protection against tumour shedding.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Received from the local medical ethics committee

## Study design

Randomised, active controlled, parallel group trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

## Health condition(s) or problem(s) studied

Colorectal cancer

## Interventions

Laparoscopic surgery compared to open surgery for colorectal cancer.

## Intervention Type

Other

**Phase**

Not Specified

**Primary outcome measure**

The amount of circulating tumour material induced by the surgical procedure, measured before, during and after the surgical procedure.

**Secondary outcome measures**

1. The level of cytokines before, during and after the surgical procedure
2. Differences in genotype between primary tumour and circulating tumour cells

**Overall study start date**

01/07/2005

**Completion date**

01/09/2006

**Eligibility****Key inclusion criteria**

1. Aged between 40 and 80 years
2. Colorectal cancer including colon and rectosigmoid cancers
3. Informed consent

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

30

**Key exclusion criteria**

1. Prior midline laparotomy
2. American Society of Anaesthesiologists (ASA) grade III/IV
3. Laparoscopic surgeon not available
4. Prior upper and/or lower midline laparotomy
5. Emergency colectomy
6. Contraindications for epidural (coagulation disorders)

**Date of first enrolment**

01/07/2005

**Date of final enrolment**

01/09/2006

## Locations

### Countries of recruitment

Netherlands

### Study participating centre

Academic Medical Centre

Amsterdam

Netherlands

1100 DD

## Sponsor information

### Organisation

Academic Medical Centre (AMC) (Netherlands)

### Sponsor details

Meibergdreef 9

Amsterdam

Netherlands

1105 AZ

### Sponsor type

University/education

### Website

<http://www.amc.uva.nl/>

### ROR

<https://ror.org/03t4gr691>

## Funder(s)

### Funder type

Other

### Funder Name

Internal funding

# Results and Publications

## Publication and dissemination plan

Not provided at time of registration

## Intention to publish date

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration