

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

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Randomised, active controlled, parallel group trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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)

ROR

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

Funder(s)

Funder type

Other

Funder Name

Internal funding

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration