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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 [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 20/12/2005	**Overall study status** Completed	
Last Edited 18/11/2008	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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