

# Influence of laparoscopy and/or fast-track multimodal management on gastrointestinal motility in comparison to open surgery and/or standard care

|  |   |  |
|--|---|--|
| <b>Submission date</b><br>20/12/2005   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered    |
| <b>Registration date</b><br>20/12/2005 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Protocol                    |
| <b>Last Edited</b><br>18/11/2008       | <b>Condition category</b><br>Cancer               | <input type="checkbox"/> Statistical analysis plan   |
|  |   | <input type="checkbox"/> Results                     |
|  |   | <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**  
Dr J. Wind

**Contact details**  
Academic Medical Centre  
P.O. Box 22660  
Amsterdam  
Netherlands  
1100 DD  
+31 (0)20 5663170  
J.Wind@amc.uva.nl

## Additional identifiers

**Protocol serial number**  
NTR276

## Study information

## **Scientific Title**

### **Acronym**

TRANSIT-study

### **Study objectives**

That minimal invasive laparoscopic surgery and/or multimodal patient care (fast-track) can prevent post-operative ileus and/or improve post-surgical gastrointestinal motility compared to open surgery and/or conventional patient care.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Received from the local medical ethics committee

### **Study design**

Randomised, double-blind, active controlled, parallel group trial

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

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

Colorectal cancer

### **Interventions**

Laparoscopic surgery and fast-track peri-operative care. At the start and at the end of the surgical procedure peritoneal lavage fluid and blood samples are collected. Cytokine levels in these samples will be determined and cells will be isolated. 24 hours post-operative a labeled test-meal will be administered orally. Abdominal scans will be made 2, 24 and 48 hours after intake of the test-meal.

### **Intervention Type**

Other

### **Phase**

Not Specified

### **Primary outcome(s)**

Gastrointestinal transit

### **Key secondary outcome(s)**

1. Clinical evaluation (passage of first stool, passage of first flatus, time till normal oral food-intake, time till discharge)
2. Intra-abdominal inflammatory status

**Completion date**

01/07/2007

## 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 IV
3. Laparoscopic surgeon not available
4. Prior upper and/or lower midline laparotomy
5. Emergency colectomy
6. Contraindications for epidural (coagulation disorders)
7. Planned stoma

**Date of first enrolment**

01/09/2005

**Date of final enrolment**

01/07/2007

## 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