# Colonic motility distal to a deviating ileostomy after rectal resection and construction of a primary anastomosis

Published: 29-09-2015 Last updated: 19-04-2024

The primary aim is to study colon motility following rectal resection with the construction of a deviating ileostomy in patients that received an enema as bowel preparation. We hypothesise that CTT is halted or decreased, similar as in patients that...

Ethical review	Approved WMO
Status	Pending
Health condition type	Anal and rectal conditions NEC
Study type	Observational invasive

# Summary

### ID

NL-OMON43557

**Source** ToetsingOnline

Brief title COLO-MOVE study

### Condition

- Anal and rectal conditions NEC
- Gastrointestinal neoplasms malignant and unspecified

**Synonym** rectal cancer, rectal carcinoma

**Research involving** Human

### **Sponsors and support**

Primary sponsor: Meander Medisch Centrum Source(s) of monetary or material Support: Voor dit onderzoek is geen financiering

1 - Colonic motility distal to a deviating ileostomy after rectal resection and cons ... 25-05-2025

nodig;dus niet van toepassing

#### Intervention

Keyword: Colon motility, Deviating ileostomy, Enema, Rectal carcinoma

#### **Outcome measures**

#### **Primary outcome**

The primary endpoint is colon motility distal to the deviating ileostomy in the early postoperative phase, which will be measured using colonic radiopaque markers (Sitzmarks®). We expect motility to be absent or minimal. In addition, the number of clinically relevant anastomotic leakages and other complications will be documented.

#### Secondary outcome

niet van toepassing

# **Study description**

#### **Background summary**

No consensus exists on the necessity of mechanical bowel preparation (MBP) for patients undergoing rectal surgery with construction of a primary anastomosis and a deviating ileostomy. For a long time, the hypothesis was that the use of MBP reduced possible dangerous complications due to anastomotic leakage. However, recent studies show no increase in complications when MBP is replaced by a preoperative enema. These results are of great clinical importance since the use of MBP is not harmless and could lead to several complications, which are not reported for an enema.

It is thought that colon transition time (CTT) is severely decreased or even halted in the early postoperative phase after rectal resection, anastomosis and construction of a protecting ileostomy. This could explain the similar complication rates following the two different bowel preparation strategies, since without colon motility, stool would never be able to pass the new anastomosis and cause complications when an anastomotic leakage is present. It is hypothesised that the decreased motility is the result of the operation itself and independent of the type of bowel preparation, which is underlined by the fact that complication rates are similar. However, so far CTT in rectal surgery has only been studied in patients that received full MBP and no studies are available for patients receiving an enema only.

#### Study objective

The primary aim is to study colon motility following rectal resection with the construction of a deviating ileostomy in patients that received an enema as bowel preparation. We hypothesise that CTT is halted or decreased, similar as in patients that received full MBP. We will compare our results with the current literature on colon motility after preparation using MBP and determine whether colon motility is dependent on the type of bowel preparation given. The eventual goal is to determine whether MBP is indeed necessary or that it is redundant and we could suffice with an enema.

### Study design

Prospective cohort study

#### Study burden and risks

All patients included in this study will have 24 colonic radiopaque markers placed in their cecum during the operation to observe colonic motility. These markers have been used as a diagnostic tool for slow-transit colon for several decades and are regarded as a safe and minimally invasive procedure. in time, the body will self excrete these markers with the feces and no additional interventions are needed to remove them from the bowel.

Movement of these markers in the colon will be monitored using abdominal X-rays (AXR) on postoperative days 1, 3, 5 and 7. These extra AXRs lead to a small additional radiation dose. However, in consultation of an independent radiologist this can be considered negligible, especially since only patients aged 50 years or older will be included. All other perioperative procedures will be conducted in accordance with standard protocol.

The potential benefits of participation in this study is a potential final answer to the much debated discussion about the optimal preoperative bowel preparation before rectal resection and the construction of a primary anastomosis and deviating ileostomy.

# Contacts

Public Meander Medisch Centrum

Maatweg 3

3 - Colonic motility distal to a deviating ileostomy after rectal resection and cons ... 25-05-2025

Amersfoort 3813TZ NL **Scientific** Meander Medisch Centrum

Maatweg 3 Amersfoort 3813TZ NL

# **Trial sites**

### **Listed location countries**

Netherlands

# **Eligibility criteria**

#### Age

Adults (18-64 years) Elderly (65 years and older)

### **Inclusion criteria**

- Age >50 years
- Established diagnosis of rectal carcinoma (confirmed by MRI and/or colonoscopy).
- Indication for rectal resection with construction of a primary anastomosis (indication determined by the treating surgeon)
- Construction of a deviating ileostomy
- Surgery performed in an elective setting
- Signed informed consent
- Preoperative bowel preparation using an enema (according to standard protocol)

### **Exclusion criteria**

- Not able to sign informed consent
- Previous colonic resection in medical history
- Known gastro-intestinal motility disorder, such as slow-transit colon, diabetic gastro-paresis etc.
- Allergy for gelatin or plastic; the radiopaque markers contain both substances
- Pregnancy

4 - Colonic motility distal to a deviating ileostomy after rectal resection and cons  $\dots$  25-05-2025

- Contra-indications for the use of either a rectal enema.

# Study design

### Design

Study type: Observational invasive		
Masking:	Open (masking not used)	
Control:	Uncontrolled	
Primary purpose:	Basic science	

### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-11-2015
Enrollment:	39
Туре:	Anticipated

# **Ethics review**

Approved WMO	
Date:	29-09-2015
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO	
Date:	03-10-2016
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

# **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 CCMO **ID** NL54501.100.15