

# Proctocolectomy and ileal pouch anal anastomosis: total mesorectal excision versus Close Rectal excision

<b>Submission date</b> 23/08/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 23/08/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 06/08/2021	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data

**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**

N/A

## Study information

### Scientific Title

Proctocolectomy and ileal pouch anal anastomosis: total mesorectal excision versus Close Rectal excision

### Acronym

Close Rectal

### Study objectives

Not much is known about the function of the pouch in relation to the space in which it is situated. At the time of construction the pouch will have a volume of +100 ml expanding over time towards its final volume + 300 ml. These data account for patients who had a proctectomy according to the Total Mesorectal Excision (TME) technique. The Close Rectal Excision (CRE) technique leaves the mesorectum in place in contrast to the TME. Theoretically, the pouch does have less space for distension. It is not known how the two techniques effect long-term pouch volume and whether this result in a difference in pouch function.

The objective of this study is to evaluate the baseline volume and distensibility of the pouch, and pouch function in patients having had restorative proctocolectomy either applying a close rectal dissection or a total mesorectal excision technique to extirpate the rectum.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Ethics approval received from the Medical Ethics Committee AMC, Amsterdam on the 26th April 2006 (ref: MEC 06/061).

### Study design

Randomised, double-blind, 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

Ileal pouch anal anastomosis

**Interventions**

Close rectal dissection of the rectum.

**Intervention Type**

Procedure/Surgery

**Phase**

Not Specified

**Primary outcome measure**

1. Baseline volume and distensibility of the pouch, measured at least one year after surgery
2. Continence, measured through questionnaires at 1, 3, 6 and 12 months following surgery
3. Quality of life, measured through questionnaires at 1, 3, 6 and 12 months following surgery

**Secondary outcome measures**

1. Morbidity
2. Blood loss

**Overall study start date**

23/06/2006

**Completion date**

01/07/2008

## Eligibility

**Key inclusion criteria**

1. Indication for proctocolectomy with construction of ileoanal pouch
2. Ulcerative Colitis or Familial Adenomatous Polyposis
3. Informed consent

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Not Specified

**Target number of participants**

30

**Key exclusion criteria**

1. Aged less than 18 years
2. American Society of Anaesthesiologists (ASA) III/IV
3. (Severe) postoperative complication
4. Emergency procedure

**Date of first enrolment**

23/06/2006

**Date of final enrolment**

01/07/2008

## **Locations**

**Countries of recruitment**

Netherlands

**Study participating centre**

**Academic Medical Centre (AMC)**

Amsterdam

Netherlands

1100 DD

## **Sponsor information**

**Organisation**

Academic Medical Centre (AMC) (The Netherlands)

**Sponsor details**

Department of Surgery

P.O. Box 22660

Amsterdam

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**Sponsor type**

Hospital/treatment centre

**Website**

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

**ROR**

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

## **Funder(s)**

**Funder type**

Hospital/treatment centre

**Funder Name**

Academic Medical Centre (AMC) (The Netherlands)

## 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

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Thesis results</a>		01/01/2014	06/08/2021	No	No