

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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr W.A. Bemelman

Contact details
Academic Medical Centre (AMC)
Department of Surgery
P.O. Box 22660
Amsterdam
Netherlands
1100 DD
+31 (0)20 566 9111
W.A.Bemelman@amc.uva.nl

Additional identifiers

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

1. Morbidity
2. Blood loss

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Not Specified

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)

ROR

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

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Academic Medical Centre (AMC) (The Netherlands)

Results and Publications

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?
Thesis results		01/01/2014	06/08/2021	No	No