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

Submission date 23/08/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 23/08/2007	**Overall study status** Completed	
Last Edited 06/08/2021	**Condition category** Surgery	

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
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Netherlands
1100 DD

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