ISRCTN35140084 https://doi.org/10.1186/ISRCTN35140084

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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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).

Primary study design
Interventional

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

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