

Female fertility after laparoscopic pouch surgery

Submission date 13/04/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 01/06/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 24/05/2012	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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Is postoperative first pregnancy rate higher after laparoscopic restorative proctocolectomy than after open restorative proctocolectomy?

Study objectives

Adhesions to the fallopian tubes are thought to be the main cause of infertility after ileal pouch-anal anastomosis (IPAA) surgery, a so-called 'tubal factor infertility'. Recent studies demonstrated a significant decrease in adhesion formation after laparoscopic abdominal surgery. Based on those study results, our hypothesis is that a higher pregnancy rate will be observed after laparoscopic IPAA compared to open IPAA, due to a reduction in adhesions of the Fallopian tubes

Ethics approval required

Old ethics approval format

Ethics approval(s)

The study protocol was approved by the ethics committee of the University Hospitals of the Catholic University in Leuven, Belgium on 30 November 2010, (B32220109939)

In the Netherlands ethics approval is not required for this study design.

Study design

Observational multicentre cross-sectional design

Primary study design

Observational

Secondary study design

Non randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Screening

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Restorative proctocolectomy and pregnancy

Interventions

1. All potential participants will be contacted for consent and thereupon a questionnaire will be sent
2. The questionnaire is developed by the departments of Obstetrics and Gynaecology and the department of Surgery at the Academic Medical Centre and it addresses patients general medical history and their desire for children both before and after IPAA
3. If patients report that there ever was a desire for children, fertility and obstetric history will be inquired after in detail

4. All self-reported patient data will subsequently be verified and completed by checking the available medical records at the hospital of the IPAA
5. Pregnancy is defined as a clinical pregnancy i.e. the presence of a fetus with a heartbeat demonstrated by ultrasound
6. Time to pregnancy is defined as the number of cycles or months between stopping contraceptives until pregnancy occurred, defined as the first day of the last menstrual period
7. Most likely, several patients will report more than one pregnancy, these pregnancies however cannot be considered as independent and therefore only the time to first pregnancy will be used in this study
8. Kaplan-Meier survival curves will be plotted for time to first pregnancy after laparoscopic or open IPAA and will be compared with a log-rank test

Intervention Type

Procedure/Surgery

Phase

Not Applicable

Primary outcome measure

Time (months) to first natural pregnancy after IPAA

Secondary outcome measures

1. Time (months) to any first pregnancy after IPAA, including pregnancies after fertility treatment
2. Subgroup analyses are planned for UC and FAP patients separately, since previous studies have shown different fertility outcomes after IPAA for these groups of patients

Overall study start date

01/02/2010

Completion date

01/04/2011

Eligibility

Key inclusion criteria

1. All living females who had IPAA between 1993 - 2009
2. IPAA in one of three tertiary referral centres in Belgium and the Netherlands
3. IPAA could be single- or two-stage and laparoscopic or open
4. At the time of IPAA patients had to be under 41 years of age
5. At the time of the study patients had to be 18 years or older

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Female

Target number of participants

A prestudy survey of all 570 IPAAAs carried out between 1993 and 2009 in the 3 centres, showed 179 eligible patients.

Key exclusion criteria

1. Refusal to participate
2. Does not meet inclusion criteria

Date of first enrolment

01/02/2010

Date of final enrolment

01/04/2011

Locations**Countries of recruitment**

Belgium

Netherlands

Study participating centre**Academic Medical Centre**

Amsterdam

Netherlands

1105 AZ

Sponsor information**Organisation**

Academic Medical Centre (Netherlands)

Sponsor details

Department of Surgery

Meibergdreef 9

Amsterdam

Netherlands

1105 AZ

Sponsor type

Hospital/treatment centre

Website

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

ROR

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

Funder(s)

Funder type

University/education

Funder Name

Academic Medical Centre (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?
Results article	cross sectional study results	01/12/2012		Yes	No