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Female fertility after laparoscopic pouch surgery

Submission date	Recruitment status	[_] Prospectively registered
13/04/2011	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
01/06/2011	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
24/05/2012	Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Willem Bemelman

Contact details
Academic Medical Centre
Department of Surgery
Meibergdreef 9
Amsterdam
Netherlands
1105 AZ

Additional identifiers

Protocol serial number
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

Study type(s)
Screening

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(s)
Time (months) to first natural pregnancy after IPAA

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

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)

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
University/education

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