# Female fertility after laparoscopic pouch surgery

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
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

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## 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 pouchanal 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

#### Kev 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

Participant information sheet