

Robotic assisted versus laparoscopic ventral rectopexy in the treatment of rectal prolapse or enterocele with secondary rectal intussusception

Submission date 12/09/2012	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 23/10/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 25/11/2019	Condition category Digestive System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

A rectal prolapse is when part of the rectum protrudes (sticks out) through the anus, or in a less severe form an internal prolapse (intussusception), when the rectum folds in on itself but doesn't stick out through the anus. It can cause pain and make it difficult to control bowel movements. Rectal prolapse can be surgically treated by laparoscopic ventral rectopexy, a keyhole operation where the rectum is suspended back into its normal position. Robot-assisted laparoscopy is a new technology which provides conditions for more precise surgery in narrow conditions. In the operation the surgeon directs robotic arms through a console by means of hand controls and pedals. Robot-assisted laparoscopy has been proven safe and feasible, but more costly and time-consuming than conventional laparoscopy. The aim of this study is to compare conventional laparoscopic ventral rectopexy to robot-assisted laparoscopy.

Who can participate?

Female patients aged between 18 and 85 with rectal prolapse requiring surgical treatment

What does the study involve?

Participants are randomly allocated into two groups, to undergo either the laparoscopic or robot-assisted operation. The effects of the surgery on pelvic floor function and quality of life are assessed using questionnaires before the operation and during follow-up visits. Follow-up visits involve a clinical examination including a gynecological examination and an MRI scan.

What are the possible benefits and risks of participating?

There is no reward paid for the participation in the study. The follow-up visits and the MRI scan are free of charge. Participation in the study carries no additional risks and the MRI scan causes no radiation exposure.

Where is the study run from?

Oulu University Hospital (Finland)

When is study starting and how long is it expected to run for?
February 2012 to August 2014

Who is funding the study?
Oulu University Hospital (Finland)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Robotic assisted versus laparoscopic ventral rectopexy in the treatment of rectal prolapse or enterocele with secondary rectal intussusception: a randomised trial

Study objectives
Robotic assisted technique may offer advantages over the conventional laparoscopic ventral rectopexy in terms of postoperative recovery, anatomic and functional results and quality of life impact.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Study design

Randomised clinical trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Rectal prolapse or enterocele with secondary intussusception

Interventions

Robotic assisted versus laparoscopic ventral rectopexy

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Current primary outcome measure as of 03/10/2019:

1. Defining the presence or absence of rectal prolapse and intussusception with/without enterocele by MR-defecography
2. Three compartment anatomy evaluation by dynamic MRI using HMO classification for measurements

Previous primary outcome measure:

Anatomic result:

1. Clinical examination: defining the presence or absence of rectal prolapse/intussusception
2. 3D endoanal ultrasound: situation of the mesh with regard to anal sphincter complex
3. MRI-defecography: objective measure of presence/absence of rectal prolapse/ intussusception

Functional result:

1. Symptom questionnaires:
 - 1.1. Obstructive Defecation Score (ODS)
 - 1.2. Wexner (for anal incontinence symptoms)
 - 1.3. Pelvic Floor Disorder Interventory (PFDI-20), including Urinary Distress Inventory 6 (UDI-6)
 - 1.4. Pelvic Organ Prolapse Distress Inventory 6 (POPDI-6) and Colorectal-Anal Distress Inventory 8 (CRADI-8)

Quality of life impact:

1. A condition specific quality of life questionnaire: Pelvic Floor Impact Questionnaire - short form 7 (PFIQ-7)
2. 15D - A generic quality of life questionnaire

Key secondary outcome(s)

Current secondary outcome measures as of 03/10/2019:

1. Functional result by symptom questionnaires:

1.1. Obstructive Defecation Score (for obstructed defecation symptoms)

1.2. Wexner score (for anal incontinence symptoms)

1.3. Pelvic Floor Disorder Interventory (PFDI-20), including Urinary Distress Inventory 6 (UDI-6), Pelvic Organ Prolapse Distress Inventory 6 (POPDI-6) and Colorectal-Anal Distress Inventory 8 (CRADI-8)

1.4 Sexual function: Pelvic Organ Prolapse / Urinary Incontinence Sexual Function Questionnaire (PISQ-12)

2. The effect on rectopexy to three compartment pelvic anatomy

2.1. Pelvic organ prolapse staging using pelvic organ prolapse quantification (POP-Q) method

Previous secondary outcome measures:

1. Operative parameters and postoperative recovery

2. Cost-benefit analysis (HRQoL by using the 15D instrument)

3. The effect on rectopexy to gynecologic organs/prolapses:

3.1. Gynaecological examination and pelvic organ prolapse staging using pelvic organ prolapse quantification (POP-Q) method

3.2. Dynamic MRI using HMO classification for measurements

4. Sexual function: Pelvic Organ Prolapse / Urinary Incontinence Sexual Function Questionnaire (PISQ-12)

Completion date

31/08/2017

Eligibility

Key inclusion criteria

1. Female patient between 18 and 85 years of age

2. Patient suitable for day-case surgery and general anaesthesia [American Society of Anesthesiologists (ASA 1-3)]

3. Previously untreated and uncomplicated rectal prolapse or enterocele

4. Isolated rectal prolapse or enterocele with intussusception

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

85 years

Sex

Female

Key exclusion criteria

1. Significant systemic illness (ASA > 4)
2. Suspicion of frozen pelvis
3. Pregnant or future plans for pregnancy

Date of first enrolment

01/02/2012

Date of final enrolment

31/08/2014

Locations

Countries of recruitment

Finland

Study participating centre

University Hospital of Oulu

Oulu

Finland

90140

Sponsor information

Organisation

University Hospital of Oulu (Finland)

ROR

<https://ror.org/045ney286>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Oulu University Hospital (Finland)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration