

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

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<b>Registration date</b> 23/10/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 25/11/2019	<b>Condition category</b> 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?  
Prof. Jyrki T Makela  
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## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

**Secondary identifying numbers**  
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)**

Ethical Committee of the Medical Faculty, University of Oulu, 14/11/2011, ref: 264

**Study design**

Randomised clinical trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

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

**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 measure**

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

## **Secondary outcome measures**

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)

## **Overall study start date**

01/02/2012

## **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

**Age group**

Adult

**Lower age limit**

18 Years

**Upper age limit**

85 Years

**Sex**

Female

**Target number of participants**

30

**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

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90140

**Sponsor information****Organisation**

University Hospital of Oulu (Finland)

**Sponsor details**

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**Sponsor type**

Hospital/treatment centre

**ROR**

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

**Funder(s)****Funder type**

Hospital/treatment centre

**Funder Name**

Oulu University Hospital (Finland)

**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