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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

Registration date
23/10/2012

Overall study status
Completed

Last Edited
25/11/2019

Condition category
Digestive System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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

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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 intussusseption: 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 intussusseption

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 intussusseption 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/intussusseption
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/ intussusseption

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 gynacologic 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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Sponsor information

Organisation
University Hospital of Oulu (Finland)

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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