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Urological and sexual function in males following robotic vs laparoscopic rectal surgery

Submission date 30/01/2017	**Recruitment status** Stopped	[X] Prospectively registered [ ] Protocol
Registration date 30/01/2017	**Overall study status** Stopped	[ ] Statistical analysis plan [ ] Results
Last Edited 05/02/2024	**Condition category** Surgery	[ ] Individual participant data [ ] Record updated in last year

Plain English summary of protocol

Background and study aims:
Rectal resection surgery is an operation to remove part or all of the rectum (the final part of the large intestine, ending in the anus). It is usually performed on patients with serious medical conditions such as rectal cancer or ulcerative colitis (a condition that causes long-term swelling (inflammation) in the large intestine and rectum). Urological (relating to urination) and sexual dysfunction are common after rectal resection surgery. This is mainly due to damage to the nerves in the pelvis during the surgery. Robotic surgery allows for precision surgery in the pelvis and can enable better preservation of those nerves. This could therefore ultimately lead to better preservation of function after rectal surgery. The aim of this study is to test find out whether robotic rectal surgery offers better urological and sexual functional outcomes when compared to standard laparoscopic (keyhole) surgery.

Who can participate?
Male sexually active adult patients requiring rectal resection surgery.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group undergo rectal resection surgery using the robotic method. Those in the second group undergo rectal resection surgery using the laproscopic method. Before surgery and then three, six and twelve months later, participants in both groups complete questionnaires about their sexual and urological function.

What are the possible benefits and risks of participating?
There are no benefits or risks involved with participation to this study. However, the results of this study could benefit others in the future.

Where is the study run from?
1. Poole Hospital (UK)
2. Frimley Park Hospital (UK)
3. Leeds Teaching Hospitals (UK)
4. Champalimaud Clinical Centre (Portugal)

When is the study starting and how long is it expected to run for?
February 2016 to February 2019

Who is funding the study?
Intuitive Surgical, Inc. (UK)

Who is the main contact?
Mr Sofoklis Panteleimonitis
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Contact information

Type(s)
Scientific

Contact name
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ClinicalTrials.gov (NCT)
211302

Integrated Research Application System (IRAS)
211302

Protocol serial number
32746

Study information

Scientific Title
Urological and sexual function in males following robotic vs laparoscopic rectal surgery: An international, multicentre, randomised control trail

Acronym
UROLE

Study objectives
The aim of this study is to evaluate the difference in urological and sexual function following two methods of minimally invasive rectal resectional surgery (robotic rectal surgery versus laparoscopic surgery).

Ethics approval required
Old ethics approval format

Ethics approval(s)
East of England - Cambridgeshire and Hertfordshire Research Ethics Committee, 20/01/2017, ref: 16/EE/0492

Primary study design
Interventional

Study design
Randomised; Interventional; Design type: Treatment, Surgery

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Specialty: Surgery, Primary sub-specialty: General Surgery; UKCRC code/ Disease: Oral and Gastrointestinal/ Other diseases of the digestive system

Interventions
Following provision of informed consent, participants are randomised to one of two groups. Stratified randomisation will take place through the use of previously filled opaque concealed envelopes. Stratification will be based on whether patients have received pre-operative chemoradiotherapy or not. An equal number of patients will be randomised for each arm. Previously filled opaque concealed envelopes will ensure concealed allocation. To ensure true randomisation envelope sequence will have been generated by a random computer-generated number sequence

Group 1: Participants receive robotic rectal surgery. This involves rectal resection surgery with a robotic surgical system platform.
Group 2: Participants receive laparoscopic rectal surgery. This involves involves rectal resection surgery via means of laparoscopic instruments.

In both groups, surgery will take place at the operating room as per unit protocol and performed by the consultant surgeon. Participants will undergo a urodynamic assessment in first instance in the outpatients clinic by the research nurse or fellow and again during colorectal surgery post-operative follow up clinics.

Following surgery, the participants in both groups will receive standard post-operative care as per unit's standard practice. Outcome measures will be assessed at 3, 6 and 12 months following surgery. This will coincide with routine post-operative surgical follow up appointments.

Intervention Type
Other

Primary outcome(s)
1. Urological function is measured using the International Prostatic Symptoms Score (IPSS) pre-operatively and 3, 6 and 12 months after surgery
2. Sexual function is measured using the International Index of Erectile Function (IIEF) pre-operatively and 3, 6 and 12 months after surgery
3. Urodynamics (urine flow rate and post micturition residual urine volume) are assessed by a uroflow meter and a bladder scanner pre-operatively and 3, 6 and 12 months after surgery

Key secondary outcome(s)
No secondary outcome measures

Completion date
01/02/2019

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
1. Patients with a diagnosis of rectal cancer (≤15 cm from anal verge on MRI staging) amenable to curative surgery OR patients with ulcerative colitis having proctectomy and ileo-anal pouch
2. Male
3. Aged 18 years and over
4. Able to provide written informed consent
5. Fit enough to undergo minimally invasive surgery (ASA≤3)
6. Deemed suitable for minimally invasive surgery by local MDT
7. Elective case
8. Sexually active (this includes caressing, foreplay, masturbation and vaginal intercourse)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
Male

Total final enrolment
0

Key exclusion criteria

1. Sexually inactive
2. Advanced tumours involving adjacent organs
3. Surgery performed with palliative intent
4. Unplanned/ emergency surgery

Date of first enrolment
01/03/2017

Date of final enrolment
01/03/2018

Locations

Countries of recruitment
United Kingdom

England

Portugal

Study participating centre
Poole Hospital
Longfleet Road
Poole
United Kingdom
BH15 2JB

Study participating centre
Frimley Park Hospital
Portsmouth Road
Frimley
United Kingdom
GU16 7UJ

Study participating centre
Leeds Teaching Hospitals
Great George Street
Leeds
United Kingdom
LS1 3EX

Study participating centre

Champalimaud Clinical Centre
Champalimaud Foundation
Champalimaud Centre for the Unknown
Avenida Brasília
Lisbon
Portugal
1400-038

Sponsor information

Organisation
Poole Hospital NHS Foundation Trust

ROR
https://ror.org/03kdm3q80

Funder(s)

Funder type
Industry

Funder Name
Intuitive Surgical, Inc.

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from UP799673@myport.ac.uk

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Other publications			05/02/2024	Yes	No
Participant information sheet	version V1.2	18/01/2017	13/02/2017	No	Yes