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Waiting list controlled trial of surgical treatment for adults with chronic constipation

Submission date
30/09/2015

Recruitment status
No longer recruiting

Registration date
30/09/2015

Overall study status
Completed

Last Edited
27/10/2022

Condition category
Digestive System

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

Plain English summary of protocol

Background and study aims
Constipation is a common condition which affects most people in their lifetime. Chronic constipation is where the sufferer has been affected for at least six months, and non-surgical treatments such as medications (laxatives), exercise and diet changes are ineffective. A laparoscopic ventral mesh rectopexy (LVMR) is a keyhole surgery procedure which is used to treat patients suffering from rectal prolapse (when the bowel slides out of the anus or slides in on itself). This procedure is designed to straighten and reattach the rectum (part of the bowel nearest to the anus) back into its normal position. The aim of this study is to find out whether LVMR could be an effective treatment for patients with chronic constipation who are unresponsive to standard treatment options.

Who can participate?
Adults with chronic constipation who are unresponsive to non-surgical treatment.

What does the study involve?
Eligible participants are randomly allocated into three groups, with different waiting times before their LVMR surgery. Those in the first group receive the surgery when they enter the study, those in the second group receive the surgery 12 weeks after entering the study, and those in the third group receive the surgery 24 weeks after entering the study. The effectiveness of the surgery on improving constipation symptoms and quality of life is measured using a number of questionnaires every 12 weeks (until 48 weeks), with the option of long term follow up to 72 weeks.

What are the possible benefits and risks of participating?
Participants may benefit from an improved quality of life as a result of taking part and will be carefully selected and monitored during the course of the study. The surgeons performing the surgery will also be carefully selected and monitored to ensure a high level of care. The risks of trial participation are very low over and above standard surgical risks and risks of anaesthesia. Radiological investigations (scans) routinely performed to select appropriate patients for surgery require a small ionising radiation dose, although this is not considered to be harmful. A number of questionnaires contain personal questions about bowel problems and the effect of these on quality of life and behaviour, which may be difficult for some participants.

Where is the study run from?
The Royal London & Whipps Cross Hospitals and nine other hospitals in England (UK)

When is the study starting and how long is it expected to run for?
July 2015 to March 2020

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Ms Natasha Stevens

Study website
http://blizard.qmul.ac.uk/capacity.html

Contact information

Type(s)
Scientific

Contact name
Mrs Shiva Taheri

Contact details
Barts and The London School of Medicine and Dentistry
Centre for Neuroscience Trauma
Blizard Institute
2 Newark Street
London
United Kingdom
E1 2AT

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
19016

Study information

Scientific Title
Stepped wedge randomised trial of laparoscopic ventral mesh rectopexy in adults with chronic constipation

Acronym

CapaCiTY03

Study objectives
This trial aims to address the evidence gap for laparoscopic ventral mesh rectopexy (LVMR) and will assess the efficacy of LVMR for the treatment of adults with chronic constipation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
First Medical Research Ethics Committee, 06/07/2015, ref: 15-LO-0609

Study design
Randomised; Interventional and Observational; Design type: Treatment, Cohort study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Chronic constipation

Interventions
Patients are randomly allocated into three groups with different waiting times for the Laparoscopic Ventral Mesh Rectopexy (LapVMR) surgery. All groups have a run in period of 4 weeks to arrange surgery, with an average waiting time of 3 months.

Group 1: The LVMR surgery is perfomed at T = 0 weeks
Group 2: The LVMR surgery is perfomed at T = 12 weeks
Group 3: The LVMR surgery is perfomed at T = 24 weeks

Within the intervention, participants are admitted to hospital for at least one day post-operative care. The stepped wedged design allows data before surgery to be compared to data after surgery, effectively, patients act as their own controls.
Post-operatively, patients are followed up after 1 day, after 30 days and once every 12 weeks to maximum 72 weeks.

Intervention Type
Other

Primary outcome measure
Patient assessment of quality of life is assessed using the Patient Assessment of Constipation Quality of Life (PAC-QOL) questionnaire at 24 weeks post-surgery compared to pre-surgery controls.

Secondary outcome measures
1. Quality of Life is measured using at 24, 48 and 72 weeks using the following questionnaires:
1.1. Patient Assessment of Constipation Symptom (PAC-SYM) total and individual domain scores
1.2. Patient Assessment of Constipation Quality of Life (PAC-QOL) total and individual domain score
1.3. Patient Health Questionnaire-9 (PHQ-9)
1.4. Generalized anxiety disorder questionnaire (GAD7)
1.5. Global patient satisfaction/improvement score (VAS) and whether they would recommend each treatment experienced to other patients
1.6. Chronic Constipation Brief Response Questionnaire (CC-BRQ), and brief illness perception questionnaire (BIPQ)
1.7. St Marks Incontinence score (for concurrent symptoms)
1.8. Baseline brief sexual function questionnaire (PISQ-12 for women and MSHQ-EjD Short Form for men)
1.9. A two week patient bowel diary (for 2 weeks prior to each assessment) to record bowel frequency and whether each evacuation was 'spontaneous (no use of laxatives) and/or complete
2. Health Economics measured at 24, 48 and 72 weeks using a patient health journal and generic quality of life using the EQ-5D-5L descriptive system and EQ-VAS
3. Specific adverse events, morbidity and mortality data measured at 24, 48 and 72 weeks using:
3.1. Perioperative findings e.g. scarring, adhesions, tissue laxity, pelvic depth, ovarian or uterine pathology
3.2. Procedural data: duration of surgery, blood loss, approach (lap vs. conversion to open), type of mesh and sutures (make, diameter, number);
3.3. Length of post-operative stay
3.4. 30 day re-admission rates;
3.5. Complications (30-day morbidity and mortality)
3.6. Specific outcomes e.g. dyspareunia and sexual function, pelvic pain, urinary dysfunction, new onset-faecal incontinence, early mesh complications (displacement, erosion, infection).
3.7. Early clinical recurrence of structural defect e.g. prolapse or rectocele based on rectal examination +/- adjunctive investigations (as clinically indicated)
4. Qualitative Interviews to assess patient and health professional experiences. Method of measurement include semi structured, digitally recorded, anonymised and transcribed interviews. Interviews will be conducted with a subset of 20 patients and 5 surgeons, before and after surgery (timing will vary depending on group allocation)

Overall study start date
01/07/2014

Completion date
01/03/2020

Eligibility

Key inclusion criteria
1. Aged between 18 and 70 years
2. Patient selfreports problematic constipation

3. Symptom onset > 6 months prior to recruitment
4. Symptoms meet American College of Gastroenterology definition of constipation
5. Constipation failed treatment to a minimum basic standard (NHS Map of Medicine 2012 (lifestyle AND dietary measures AND =2 laxatives or prokinetics) tried (no time requirement)
6. Ability to understand written and spoken English (due to questionnaire validity)
7. Ability and willingness to give informed consent
8. Failure of nonsurgical interventions (minimum of nurse led behavioural therapy)
9. Internal rectal prolapse as determined by clinical examination and INVEST

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 114; UK Sample Size: 114; Description: 1:1:1 AllocationGrp 1: Lap VMR at T (0) = 38Grp 2: Lap VMR at T(12) = 38Grp 3: Lap VMR at T(24) = 38

Total final enrolment
28

Key exclusion criteria
1. Significant organic colonic disease (red flag symptoms e.g. rectal bleeding prior investigated); IBD; megacolon or megarectum (if diagnosed beforehand); severe diverticulosis/stricture/birth defects deemed to contribute to symptoms (incidental diverticulosis if known not an exclusion)
2. Major colorectal resectional surgery
3. Current overt pelvic organ prolapse (bladder, uterus) or disease requiring obvious surgical intervention other than lap VMR
4. Previous rectopexy
5. Sacral nerve stimulation (SNS) in situ
6. Rectal impaction (as defined by digital and abdominal examination: these form part of the NHS Map of Medicine basic standard)
7. Significant neurological disease deemed to be causative e.g. Parkinson’s, spinal injury, multiple sclerosis, diabetic neuropathy (not uncomplicated diabetes alone)
8. Significant connective tissue disease: scleroderma, systemic sclerosis and SLE (not hypermobility alone)
9. Significant medical comorbidities and activity of daily living impairment (based on Bartell index in apparently frail patients Barthel index <=11)
10. Major active psychiatric diagnosis (e.g. schizophrenia, major depressive illness and mania)
11. Chronic regular opioid use (at least once daily use) where this is deemed to be the cause of constipation based on temporal association of symptoms with onset of therapy
12. Pregnancy or intention to become pregnant during study period
13. Known severe intraabdominal adhesions

Date of first enrolment
01/07/2015

Date of final enrolment
30/06/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The Royal London & Whipps Cross Hospitals
Barts Health NHS Trust
Whitechapel Road
London
United Kingdom
E1 1BB

Study participating centre
St Thomas' Hospital
Westminster Bridge Road
Guy's and Thomas' NHS Foundation Trust
London
United Kingdom
SE1 7EH

Study participating centre
Wythenshawe Hospital
University Hospital of South Manchester NHS Foundation Trust
Southmoor Road
Wythenshawe
Manchester
United Kingdom
M23 9LT

Study participating centre
Northern General Hospital
Sheffield Teaching Hospital NHS Foundation Trust
Herries Road
Sheffield

United Kingdom
S5 7AU

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

Study participating centre
Southmead Hospital
North Bristol NHS Foundation Trust
Southmead Road
Westbury-on-Trym
Bristol
United Kingdom
BS10 5NB

Study participating centre
Royal Shrewsbury Hospital
The Shrewsbury and Telford Hospital NHS Trust
Mytton Oak Road
Shrewsbury
United Kingdom
SY3 8XQ

Study participating centre
Broomfield Hospital
Mid Essex Hospital Services NHS Trust
Court Road
Chelmsford
United Kingdom
CM1 7ET

Study participating centre
St. James's University Hospital
The Leeds Teaching Hospitals NHS Trust

Leeds
United Kingdom
LS9 7TF

Study participating centre
Southend University Hospital NHS Foundation Trust
Prittlewell Chase
Southend-on-Sea
Westcliff-On-sea
United Kingdom
SS0 0RY

Sponsor information

Organisation
Queen Mary University of London

Sponsor details
-
London
England
United Kingdom
E1 4NS

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/026zzn846

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Publication is planned in July 2021. Scientific findings will be subjected to international reporting and peer review (targeting appropriate clinical journals e.g. BMJ, Lancet or Gastroenterology). The assimilation of data from this trial with those from other studies and convening of a national CC working group to consider the findings will lead to prototype national guidance that will inform NHS pathway development and commissioning of services. As such, it will be logical to initiate discussions with NICE for the development of a guideline for the management of CC in adults and to progress adoption by specialist medical and nursing organisations. Although the development of this guidance should naturally facilitate dissemination of the main programme findings to health care planners, policy makers and practitioners, we will also direct this information (and that of individual studies) to the following groups; Study participants and carers, charity links and patient groups, local health service providers, The Primary Care Society for Gastroenterology, school children via interactive learning tools and the NIHR HTC. Finally, we will repeat the highly successful 2 day international meeting entitled 'Current perspectives in chronic constipation' organised by Dr Scott and hosted by QMUL in February 2009 which was attended by over 250 scientists and clinicians and led to a supplement in the journal Neurogastroenterology & Motility dedicated to CC. This meeting is planned again for 2019 to coincide with the outputs of the programme.

Intention to publish date
01/07/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a repository held by the Barts and the London Pragmatic Clinical Trials Unit, Queen Mary University of London.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version V3		03/05/2016	No	Yes
Protocol article	protocol	05/02/2018		Yes	No
Results article		19/05/2022	23/05/2022	Yes	No
Results article		01/11/2021	27/10/2022	Yes	No