ISRCTN11093872 https://doi.org/10.1186/ISRCTN11093872

CapaCiTY Study 2 - Chronic Constipation Treatment Pathway

Submission date
11/11/2015

Recruitment status
No longer recruiting

Registration date
11/11/2015

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 at some point in their lives. Chronic constipation is where the sufferer has been affected for at least six months, and basic treatments such as medications (laxatives), exercise and diet changes are ineffective. Another type of therapy is behaviour therapy, where a nurse helps the sufferer to use their muscles properly while straining. This type of therapy can be very effective, although it can be very time-consuming and may interfere with a patient's day to day life. Anal irrigation, also known as trans-anal irrigation, is a technique where waste material (faeces) is flushed out of the bowel. During the procedure, water is pumped into the bowel through a tube inserted into the rectum (bottom), which essentially "rinses" it. The water is then removed from the bowel, taking the faeces with it. This type of procedure can be done using a large amount of water (high volume trans-anal irrigation) or a smaller amount of water (low volume trans-anal irrigation. The high volume technique is able to reach more of the bowel, but many patients are not able to cope with the procedure. The low volume technique only reaches the lower part of the bowel but it does cause the patient as much discomfort. The aim of this study is to compare the high and low volume techniques of anal irrigation in patients with chronic constipation to find out which is the most effective and cost-effective procedure.

Who can participate?
Adults with chronic constipation who are unresponsive to nurse-led behavioural therapy and are willing to try anal irrigation.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group undergo low volume anal irrigation and those in the second group undergo high volume anal irrigation. At the start of the study and three months after the anal irrigation procedure, participants in both groups are asked to complete a questionnaire to assess their quality of life.

What are the possible benefits and risks of participating?
Participants benefit from receiving a very high standard of monitored care throughout the study. There are very minor risks of undergoing anal irrigation, however there is a small risk of pain, bleeding, painful haemorrhoids and anal fissure (tear).

Where is the study run from?
12 hospitals in England (UK)

When is the study starting and how long is it expected to run for?
August 2015 to February 2019

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

Who is the main contact?
Mrs Shiva Taheri
s.taheri@qmul.ac.uk

Study website
http://www.blizard.qmul.ac.uk/teaching/40-undergraduate/1190-capacity-study.html

Contact information

Type(s)
Public

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
+44 (0)20 7882 6031
s.taheri@qmul.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
18979

Study information

Scientific Title
Pragmatic randomised trial of low versus high volume initiated transanal irrigation therapy in adults with chronic constipation

Study objectives
The aim of this trial is to assess the effectiveness and cost effectiveness of low volume and high volume trans-anal irrigation therapy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
First Medical Research Ethics Committee, 06/07/2015, ref: 15/LO/0732

Study design
Randomised parallel trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Other

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
Topic: Surgery, Gastroenterology; Subtopic: Gastroenterology; Disease: All Gastroenterology

Interventions
Before randomisation, patients will undergo radiophysiological investigations (INVEST) and the relationship between these test results and response to treatment will also be explored. Eligible patients are then randomly allocated to 2 groups.

Group 1: Participants receive low volume anal irrigation, which irrigates the lower part of rectum
Group 2: Participants receive high volume anal irrigation, which irrigates a higher volume of rectum

Anal irrigation training is based on NHS routine care. Patients will undergo a single nurse-led training session before starting treatment. The irrigation journal consists of, volume of water introduced, frequency of use adverse events and side effects e.g. pain, bleeding. Start date for home irrigation agreed with the patient (this is to allow for any delay in delivery of equipment). Ideally this should be the same day as Visit 2, or within 1 week maximum. If there are problems then a further face-to-face training session will be offered, including a review of adverse events and concomitant medications. This can occur any time before visit 3 (2 weeks +/- 1 week from visit 2.1) or in conjunction with visit 3 if not before. Patients will continue the self-administered therapy using a commercially-available device until the end of the study. Patients will be

followed up until the end of the data collection phase of the study or until they decide to discontinue either the therapy or the trial follow up. Irrigation will be performed at an agreed frequency initially. Once established on this therapy patients may adjust the frequency and volume of irrigation to suit their particular condition.

The intervention period is 1 month and follow up period is 12 months.

Intervention Type
Other

Primary outcome measure
Quality of life is measured using the Patient Assessment of Constipation Quality of Life questionnaire (PAC-QOL35, 36) at 3 months.

Secondary outcome measures
1. Disease specific outcomes are measured using PAC-QOL score and individual domain scores at baseline, 1, 3, 6, and 12 months
2. Time to cessation of each system of irrigation and total time in treatment with either system is determined using the irrigation journal at baseline, 1, 3, 6, and 12 months
3. Reason for cessation of each system is determined using the irrigation journal and qualitative interviews at baseline, 1, 3, 6, and 12 months
4. Disease specific outcomes are measured using Patient Assessment of Constipation Symptoms (PAC-SYM): aggregate and domain scores at baseline, 1, 3, 6, and 12 months
5. Volume and duration of irrigation (irrigation journal) at baseline, 1, 3, 6, and 12 months
6. Number and nature of bowel motions (captured in 2-week patient diary) at baseline, 3, 6 and 12 months
7. Symptom scores derived from diary records are taken over two weeks before or around each follow-up contact (these will include number of spontaneous complete bowel motions) at baseline, 3, 6 and 12 months
8. Disease specific outcomes are measured using Generalized anxiety disorder questionnaire (GAD7) at baseline, 3, 6 and 12 months
9. Disease specific outcomes are measured using Depression, anxiety and somatisation modules of the PHQ-9 at baseline, 3, 6 and 12 months
10. Disease specific outcomes are measured using Global patient satisfaction/improvement score (VAS) at baseline, 3, 6 and 12 months
11. Patient acceptability and recommendation to other patients is assessed using qualitative interviews
12. Disease specific outcomes are measured using Behavioural response to illness questionnaire (CC-BRQ), and brief illness perception questionnaire BIPQ (CC) at baseline, 3, 6 and 12 months
13. Generic quality of life is measured using EuroQol EQ-5D-5L and EQ-VAS at baseline, 1, 3, 6, and 12 months
14. Use of healthcare resources, adverse events, and concomitant medications is collected using patient journals at baseline, 3, 6, and 12 months

Overall study start date
01/08/2015

Completion date
31/12/2019

Eligibility

Key inclusion criteria
1. Aged between 18 and 70 years
2. Patient self reports problematic constipation
3. Symptom onset > 6 months before 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 previous nurse-led behavioural therapy
9. Ability of patient / carer to use anal irrigation

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 300; UK Sample Size: 300; Description: Low volume irrigation therapy arm n=150High volume irrigation therapy arm n=150

Key exclusion criteria
1. Significant organic colonic disease (red flag symptoms e.g. rectal bleeding previously investigated); IBD; megacolon or megarectum (if diagnosed beforehand) [the study will provide a useful estimate of the prevalence of such cases in referral practice]; severe diverticulosis /stricture/birth defects deemed to contribute to symptoms (incidental diverticulosis not an exclusion)
2. Major colorectal resectional surgery
3. Current overt pelvic organ prolapse (bladder, uterus, vagina, rectum) or disease requiring surgical intervention
4. Previous pelvic floor surgery to address defaecatory problems: posterior vaginal repair, STARR and rectopexy;previous sacral nerve stimulation
5. Previous use of transanal irrigation therapy to treat constipation
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 of constipation 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, Bartel index <=11)
10. Physical disability/impairment which prevents use of one or other of the irrigation devices
11. Major psychiatric diagnosis (e.g. schizophrenia, major depressive illness, mania, self harm and

drug/alcohol addiction)
12. 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; all regular strong opioid use
13. Pregnancy or intention to become pregnant during study period

Date of first enrolment
25/08/2015

Date of final enrolment
30/06/2018

Locations

Countries of recruitment
England

Scotland

United Kingdom

Study participating centre
Royal London Hospital
Bart's Health NHS Trust
Whitechapel Road
London
United Kingdom
E1 1BB

Study participating centre
St Marks Hospital
London North West Healthcare NHS Trust
Watford Road
Harrow
United Kingdom
HA1 3UJ

Study participating centre
University College Hospital
235 Euston Road
Fitzrovia
London
United Kingdom
NW1 2BU

Study participating centre
St Thomas' Hospital
Westminster Bridge Road
London
United Kingdom
SE1 7EH

Study participating centre
University Hospital of North Durham
County Durham and Darlington NHS Foundation Trust
North Road
Durham
United Kingdom
DH1 5TW

Study participating centre
University Hospital of South Manchester
Southmoor Road
Manchester
United Kingdom
M23 9LT

Study participating centre
Homerton University Hospital
Homerton Row
London
United Kingdom
E9 6SR

Study participating centre
Northern General Hospital
Herries Road
Sheffield
United Kingdom
S5 7AU Phone: 0114 243 4343

Study participating centre
Royal Victoria Infirmary
Queen Victoria Road

Newcastle upon Tyne
United Kingdom
NE1 4LP

Study participating centre
Whiston Hospital
St Helens & Knowsley Teaching Hospitals NHS Trust
Legal Offices, Nightingale House
LG1
Warrington Road
Prescot
United Kingdom
L35 5DR

Study participating centre
Western General Hospital
Crewe Road South
Edinburgh
United Kingdom
EH4 2XU

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

Sponsor information

Organisation
Queen Mary University of London (UK)

Sponsor details
Joint Research Management Office
5 Walden Street
London
England
United Kingdom
E1 2EF

Sponsor type

University/education

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
All publications using data from this trial to undertake original analyses will be submitted to the PSC for review before release. To safeguard the scientific integrity of the trial, data will not be presented in public before the main results are published without the prior consent of the PSC.

Intention to publish date
31/07/2020

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	31/03/2017		Yes	No

Results article	01/11/2021	27/10/2022	Yes	No
HRA research summary		28/06/2023	No	No