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Efficiency of transanal irrigation and stimulation of a nerve of the ankle to improve symptoms and quality of life after radical surgery of rectal cancer

Submission date
03/03/2017

Recruitment status
No longer recruiting

Registration date
14/03/2017

Overall study status
Completed

Last Edited
08/10/2019

Condition category
Surgery

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

Plain English summary of protocol

Background and study aims
Rectal cancer (cancer of the rectum) affects the lower part of the colon that connects to the anus. In many patients undergoing surgery to remove rectal cancer (and who have also received radiotherapy) the anus is not removed and patients may continue to defecate through this natural route. However, the removal of all or part of the rectum can cause faecal incontinence (involuntary leakage of faeces), urgency (must urgently seek a toilet), and fragmentation of the stool which forces them to perform small and repeated defecations. There is no specific treatment that improves these symptoms. This study compares the effects of two non-invasive and non-painful procedures for this situation. Transanal irrigation using a mechanical device (Peristeen®) attempts to empty the stool at once, allowing a normal life until the bowel is filled again with faeces. Electrical stimulation through a nerve in the leg (tibial nerve) can be used to improve the sensitivity and strength of the muscles of the pelvis and improve their ability to contain and expel the stool. The aim of this study is to compare the effects of Peristeen and tibial nerve stimulation in patients who have problems with continence and expulsion of feces that affect their quality of life and daily activities.

Who can participate?
Patients aged 20 to 80 who have been operated on for rectal cancer at least one year before the study

What does the study involve?
Participants are randomly allocated to be treated with either transanal irrigation using Peristeen® or posterior tibial nerve stimulation. The severity of their symptoms is recorded at the start of the study and after 12, 18 and 24 weeks.

What are the possible benefits and risks of participating?
The possible benefits for the patients are the improvement of symptoms of faecal incontinence, allowing them to lead a more active life. The treatments proposed for the study are safe, and

there are no complications associated with their use. The worst that can happen is that they do not work. With transanal irrigation, there may be a problem with the rectal catheter placement and some rectal perforation has been described, but it is estimated that this occurs in one of 100,000 irrigations.

Where is the study run from?
Hospital Universitario Donostia (Spain)

When is the study starting and how long is it expected to run for?
April 2017 to April 2018

Who is funding the study?
Hospital Universitario Donostia (Spain)

Who is the main contact?
Dr Jose M Enriquez-Navascues

Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
JME-DON-2017-03

Study information

Scientific Title
Transanal irrigation and percutaneous tibial nerve stimulation in the treatment of anterior resection syndrome after rectal cancer resection

Acronym
PTNS/TAI

Study objectives
Transanal irrigation and percutaneous posterior tibial nerve stimulation are able to decrease the postoperative Low Anterior Resection Syndrome (LARS) score

Ethics approval required
Old ethics approval format

Ethics approval(s)
Hospital Donostia Ethics Committee, 21/03/2017

Study design
Open categorized interventional parallel assignment 1:1 multicentre randomized 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
Patients operated for rectal cancer with sphincter preservation and poor postoperative intestinal function

Interventions
The randomization sequence will be performed by a computerized randomization algorithm integrated in the program (R v2.9). Patients are randomized to:
1. Transanal irrigation (TAI) with a device (Peristeen, Coloplast DK). Transanal irrigation is performed using the Peristeen system. This consists of a bag that is filled with up to 1000 cc of lukewarm tap water, a coated rectal catheter with a retaining balloon which is inserted in the neorectum, a control unit for the regulation of air and water and a pump for inflating the balloon and for irrigating the rectum. Patients are instructed by a trained stoma nurse for 3-4 weeks; once the patient is familiar with the procedure, he or she can do it independently at home. Test scores are recorded at baseline, 12, 18 and 24 weeks.
2. Posterior tibial nerve stimulation (PTNS) (Urgent PC, Uroplasty, Nl). PTNS consists of the insertion of a small electrode above the medial malleolus adjacent to the posterior tibial nerve. An adhesive surface is placed under the arch of the foot. Both electrodes are connected to the neurostimuator that generates electricity. A neuromodulation session last 30 minutes. The

treatment plan includes 12 weekly sessions, followed by two sessions at two weeks' intervals. Test scores are recorded at baseline, 12, 18 and 24 weeks.

Intervention Type
Device

Primary outcome measure
Severity of LARS, measured using the Low Anterior Resection Syndrome scale (LARS) at baseline, 12, 18 and 24 weeks

Secondary outcome measures
Measured at baseline, 12, 18 and 24 weeks:
1. Fecal incontinence, measured using Vaizey's score
2. Dysfunctional defecation, measured using Altomare's score
3. Quality of life, measured using the QLQ-C30 Score
4. Patient satisfaction, measured using the VAS

Overall study start date
01/04/2017

Completion date
01/04/2018

Eligibility

Key inclusion criteria
1. Patients operated on for rectal cancer with sphincter preservation and functional anastomosis at least one year before study
2. Aged 20 to 80

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
28

Total final enrolment
27

Key exclusion criteria
1. IBD
2. IBS
3. Pregnancy
4. Other intestinal resection segments different from the rectum

5. Metastatic disease
6. Previous history of SNS or PTNS
7. Severe postflebitic syndrome
8. Pacemaker or defibrillator
9. Neurological disorders

Date of first enrolment
01/04/2017

Date of final enrolment
01/10/2017

Locations

Countries of recruitment
Spain

Study participating centre
Hospital Universitario Donostia
San Sebastian
Spain
20014

Sponsor information

Organisation
Hospital Universitario Donostia

Sponsor details
Colorectal Unit
Pº Dr Beguiristain s/n
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04fkwzm96

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Hospital Universitario Donostia

Results and Publications

Publication and dissemination plan
The trialist plan to publish in a peer reviewed journal in the field of Gastrointestinal Surgery or Coloproctology three months after finalizing the collection and analysis of data.

Intention to publish date
30/04/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Jose M Enríquez-Navascués

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2020	08/10/2019	Yes	No