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Use of physiotherapy to improve bowel function after rectal cancer surgery

Submission date
06/11/2017

Recruitment status
No longer recruiting

Registration date
02/01/2018

Overall study status
Completed

Last Edited
24/02/2023

Condition category
Cancer

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

Plain English Summary
Background and study aims
Up to 75% of patients experience difficulty controlling their bowels for up to 12 months following surgery for rectal cancer and 1 in 4 will continue to do so for more than a year. The introduction of an education session from specialist nurses and physiotherapists prior to surgery to teach patients how to improve their bowel function using a pelvic floor programme could be helpful. By assessing muscle tone in the pelvis before and after surgery to see if the introduction of pelvic floor training will determine if the programme is acceptable to patients and if they are able to comply with the programme at may be a stressful time for themselves and their family. In addition to evaluating the programme patients are interviewed to assess their satisfaction with the elements of the programme. This study is hoped to initiate further studies in future to look at the impact of introducing this intervention on bowel function and the effect on quality of life and function for bowel cancer survivors. The aim of this study is to test the feasibility of a simple intervention to improve bowel function following surgery for rectal cancer.

Who can participate?
Adults aged 18 and older with rectal cancer.

What does the study involve?
Patients recruited into this study are given an educational session to inform patients of bowel problems that can occur after surgery, simple measures to improve them and also education around pelvic floor exercises. Following this patients have an assessment of their pelvic floor by a physiotherapist and are given a tailored programme of exercises to follow for 12 weeks following their surgery, with two appointments at six and 12 weeks to assess progress. They are asked to complete questionnaires on quality of life and bowel function before surgery and after surgery (six and 12 weeks).

What are the possible benefits and risks of participating?
Participants may benefit from increased education and the potential for improvements in bowel function after rectal cancer surgery. There are no direct risks to patients involved in the study.

Where is the study run from?
1. Royal Glamorgan Hospital (UK)

2. University Hospital of Wales (UK)
3. Prince Charles Hospital (UK)

When is the study starting and how long is it expected to run for?
September 2016 to October 2018

Who is funding the study?
Tenovus (UK)

Who is the main contact?
Mrs Julie Cornish

Contact information

Type(s)
Scientific

Contact name
Mrs Julie Cornish

Contact details
Department of Surgery
Cwm Taf University Health Board
Llantrisant
United Kingdom
CF728XR

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2.0

Study information

Scientific Title
Physiotherapy and Anterior Resection Syndrome

Acronym
PARiS

Study hypothesis
The aim of this study is to test the feasibility of introducing a simple intervention in an attempt to improve bowel function following surgery for rectal cancer. We propose the introduction of an educational session from specialist nurses and physiotherapists prior to surgery to teach

patients how to strengthen their pelvic floor using this programme. The primary aim of this study is to see if the introduction of pelvic floor training is acceptable to patients and if they are able to comply with the programme at what may be a stressful time for themselves and their family.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Wales REC 6, 21/04/2016, ref: REC 16/WA/0124

Study design
Feasibility non randomised study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use contact details to request patient information sheet

Condition
Rectal Cancer

Interventions
Participants undergo an educational Session and Pelvic Floor Rehabilitation programme.

Patients recruited into this study are given an educational session to inform patients of bowel problems that can occur after surgery, simple measures to improve them and also education around pelvic floor exercises. Following this participants have an assessment of their pelvic floor by a physiotherapist and be given a tailored programme of exercises to follow for 12 weeks following their surgery, with two appointments at six and 12 weeks to assess progress. They are asked to complete questionnaires on quality of life and bowel function before surgery and after surgery (six and 12 weeks).

Intervention Type
Behavioural

Primary outcome measure
Proportion of eligible patients approached who consent and attend the educational session are measured using the screening log and attendance record at each site.

Secondary outcome measures

1. Compliance with PFR programme is measured using Squeezy app +/-patient diaries for 12 weeks. Data will be collected at 6 and 12 weeks from the patients records
2. Acceptability of the intervention to the patient is measured using qualitative interviews for a proportion of patients (8-12) following the educational session and following the pelvic floor programme as 12 weeks
3. Pelvic floor tone measured using the Oxford Grading System, ICS grading system at the baseline assessment, 6 weeks and 12 weeks postoperatively
4. Patient bowel function is measured using LARS score and St Marks Faecal Incontinence Score at the baseline assessment, 6 weeks and 12 weeks postoperatively
5. Patient quality of life is measured using EQ5D, EORTC QLQ C30 and CR29, qualitative interviews at the baseline assessment, 6 weeks and 12 weeks postoperatively
6. Opinion on physiotherapy programme DVD are measured using focus groups following completion of the 12 week programme

Overall study start date
01/09/2016

Overall study end date
01/10/2018

Eligibility

Participant inclusion criteria
1. 18 years old
2. Rectal cancer
3. Undergoing Anterior Resection procedure with planned intestinal continuity
4. Able to complete physiotherapy programme

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40

Total final enrolment
9

Participant exclusion criteria
1. Unable to give informed consent
2. Not physically capable of performing the PFR programme

Recruitment start date
01/09/2017

Recruitment end date
01/09/2018

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Royal Glamorgan Hospital
Llantrisant
United Kingdom
CF728XR

Study participating centre
University Hospital of Wales
Cardiff
United Kingdom
CF144XW

Study participating centre
Prince Charles Hospital
Gurnos Roadd
Merthyr Tydfil
United Kingdom
CF47 9DT

Sponsor information

Organisation
Cwm Taf University Health Board

Sponsor details
Royal Glamorgan Hospital
Llantrisant
Wales

United Kingdom
CF728XR

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00rh52j13

Funder(s)

Funder type
Charity

Funder Name
Tenovus

Alternative Name(s)
Tenovus Cancer Care

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high impact peer reviewed journal. Planned publication of the protocol.

Intention to publish date
30/09/2019

Individual participant data (IPD) sharing plan
The dataset generated during the study is available upon request until 01/03/2028. Anonymised demographic, medical, patient-reported outcome and study-specific metric data may be shared with bonafide researchers, for use in research projects carried out in the public interest within the context of medical care or treatment. Access requests are processed according to local NHS policy and procedure and access may be granted at the discretion of the Chief Investigator/ Data

Controller, who reserves the right to fully or partially withhold data. Further information, including application enquiries, should be made in writing to Mrs Julie Cornish at ColorectalResearch.CAV@wales.nhs.uk.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	30/06/2018	18/10/2019	Yes	No
Results article		26/09/2022	24/02/2023	Yes	No
HRA research summary			28/06/2023	No	No