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Transcutaneous vagal nerve stimulation & postoperative bowel function

Submission date 16/10/2017	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 18/10/2017	**Overall study status** Completed	
Last Edited 13/09/2021	**Condition category** Digestive System	

Plain English summary of protocol

Background and study aims
Surgery on the bowel often leads to postoperative ileus (POI) - a condition in which the bowel "goes to sleep". In most patients, the bowel soon returns to normal, but in some patients POI is prolonged. This delays recovery and increases the risk of vomiting, constipation, breathing difficulties, and blood clots in the legs and lungs. A new device aims to minimise the occurrence of POI by stimulating the nerves to the bowel and reducing the time taken for return of normal bowel function. It is easy to use, has no known serious side-effects and the device can be used at home or in hospital. There is currently no effective treatment for POI. The aim of this study is to investigate whether the new treatment (stimulating the nerves to the bowel using a simple and safe device) will provide a much-needed solution to a long-standing problem and make surgery safer for patients.

Who can participate?
Adults aged 17 and older who have a confirmed colorectal cancer

What does the study involve?
Participants are randomly allocated to one of two groups. Participants in the first group receive a device to usetwice a day. Participants in the second group receive a "dummy" device which looks and feels the same but does not produce nerve stimulation. The treatment will be assessed in several ways, including: time taken for the bowel to recover, blood tests before and after surgery, an MRI scan to look at the bowel and patients' acceptance of the device.

What are the possible benefits and risks of participating?
Participants may benefit from improvement in their symptoms. There are no expected risks with participating.

Where is the study run from?
St. James's University Hospital (UK)

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

Who is funding the study?
Bowel Disease Research Foundation (BDRF) (UK)

Who is the main contact?
Mr Stephen Chapman
stephen.chapman@doctors.org.uk

Contact information

Type(s)
Public

Contact name
Mr Stephen Chapman

ORCID ID
https://orcid.org/0000-0003-2413-5690

Contact details
-
Leeds
United Kingdom
-

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
35914

Study information

Scientific Title
An investigation of transcutaneous vagal nerve stimulation on return of bowel function and inflammatory markers after colorectal surgery

Study objectives
The aim of the study is to investigate the effect of transcutaneous vagal nerve stimulation on the return of bowel function after colorectal surgery

Ethics approval required
Old ethics approval format

Ethics approval(s)
North East: Tyne & Wear South Research Ethics Committee, 24/04/2017, ref: 17/NE/0091

Study design
Randomised; Interventional; Design type: Treatment, Prevention, Device

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 below to request a patient information sheet

Health condition(s) or problem(s) studied
Colorectal Surgery

Interventions
Participants self-administer a hand held, non-invasive, vagal nerve stimulator device before and and after surgery.
Half of patients will have a functioning device and the other half will have a “dummy” device which looks and feels the same but does not produce nerve stimulation. This will allow the effect of the functioning device to be compared.

Bowel function is assessed daily, as well as postoperative assessments of systemic cytokine response and small bowel motility.

Intervention Type
Other

Phase
Phase II

Primary outcome measure
Time taken to first bowel movement is measured according to daily clinical enquiry.

Secondary outcome measures
1. Time to first flatus is measured according to daily clinical enquiry
2. Time to oral tolerance (solid food in the absence of vomiting) is measured according to daily clinical enquiry
3. Serum cytokines IL1b, IL6 & TNFα are measured by blood draw on postoperative days 1 and 3
4. Small bowel motility is measured using a quantitative score generated by Magnetic resonance enterography (MRE) studies

Overall study start date

01/01/2017

Completion date
01/12/2019

Eligibility

Key inclusion criteria
1. Aged greater than 17 years
2. Able to provide written informed consent
3. Able to use the device and comply with study procedures
4. Confirmed diagnosis of colorectal cancer via radiological or histological modalities
5. Undergoing elective laparoscopic colorectal resection

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 40; UK Sample Size: 40

Total final enrolment
40

Key exclusion criteria
1. Acute infective or inflammatory condition
2. Pre-operative, therapeutic radiotherapy
3. Previous MI (STEMI/NSTEMI) or cerebrovascular disease (CVA/TIA) or known peripheral vascular disease
4. Known congestive heart failure (NYHA>2),
5. Known cardiac dysrhythmia (Previous VF, VT, AF, SVT, Heart block)
6. Known history of seizures or recurrent syncope in the last five years
7. Known chronic inflammatory condition of the gastrointestinal tract
8. Previous neck surgery, or other abnormality distorting the cervical anatomy
9. Previous vagotomy at any anatomical location
10. Any in-dwelling device, stimulator or non MR compatible metallic implant
11. Known or suspected intra-occular metallic bodies
12. Regular medication known to mediate systemic inflammation (e.g. NSAIDS)
13. Psychiatric, cognitive or behavioural problems which may affect study procedures
14. Belonging to a vulnerable population (homeless, prisoner)
15. Current pregnancy

Date of first enrolment
01/11/2017

Date of final enrolment
31/08/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
St. James's University Hospital
Beckett Street
Leeds
United Kingdom
LS9 7TF

Sponsor information

Organisation
University of Leeds

Sponsor details
Leeds
Leeds
England
United Kingdom
LS2 9JT

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
Government

Funder Name
Bowel Disease Research Foundation (BDRF)

Results and Publications

Publication and dissemination plan
Publication in a high-impact peer reviewed journal is planned within one year of trial closure (estimated 2018-2019).

Intention to publish date
31/03/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request. Proposals for further analyses should be submitted to the principal investigator (Stephen Chapman; stephen.chapman@doctors.org.uk) which will be reviewed by a statistician. If considered to be feasible, the proposer will be invited to work with the study team to undertake the analysis and reporting of results.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/05/2021	13/09/2021	Yes	No
HRA research summary			28/06/2023	No	No