# Transcutaneous vagal nerve stimulation & postoperative bowel function

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

### 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

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Leeds United Kingdom

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# Additional identifiers

#### Protocol serial number

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

## Study type(s)

Treatment

## 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(s)

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

## Key secondary outcome(s))

- 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 & TNFa 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

# 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

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Sex

All

#### 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

United Kingdom

England

## Study participating centre St. James's University Hospital

Beckett Street Leeds United Kingdom LS9 7TF

# Sponsor information

#### Organisation

University of Leeds

#### **ROR**

https://ror.org/024mrxd33

# Funder(s)

#### Funder type

Government

#### **Funder Name**

Bowel Disease Research Foundation (BDRF)

# **Results and Publications**

# 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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes