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A comparison of two medical devices that assess how people sense the need to empty their bowels

Submission date 24/02/2025	**Recruitment status** Recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 21/07/2025	**Overall study status** Ongoing	
Last Edited 21/07/2025	**Condition category** Digestive System	

Plain English summary of protocol

Background and study aims

The human body stores stool (poo) within the rectum, which is between the end of the large bowel and the anus, where stool exits the body. Some people develop issues with sensing that stool is there, or can sense it too much. This can cause symptoms that decrease quality of life, such as leaking stool, pain, and going to the toilet too much or too little. One example where this occurs is a condition called irritable bowel syndrome, which currently affects 3.2 million people in the UK.

The majority of hospitals in the UK assess sensations felt within the rectum by inflating a small elastic (stretchy) balloon, placed within the rectum, with air. The patient is asked at what time they feel different sensations, and from this information a diagnosis can be made (using the London Classification system), which can help their doctor to devise a treatment plan. A less common device, called a rectal barostat, can also be used to test sensations in the rectum. Instead of an elastic balloon, the rectal barostat inflates a plastic bag that is non-elastic, with air. Since the rectal barostat bag is non-elastic, it can also measure the capacity of the rectum, and tell us how stretchy its walls are. In this study, patients who attend for the elastic balloon test as part of standard care, would also undergo assessment with the rectal barostat in the same hospital appointment. This study aims to find out whether patients tested with the elastic balloon receive the same diagnosis as when they are tested with the rectal barostat. This research is important as it may show that using the rectal barostat changes someone's diagnosis, and suggests more centres should be using this device instead of the elastic balloon so we can accurately diagnose more patients.

Who can participate?

Patients aged over 18 and under 90 years who meet one or more of the following indications for anorectal physiology investigations: symptoms of constipation or disorder of evacuation, faecal incontinence, functional anorectal pain, faecal urgency and frequency of moving bowels, constant urge to move bowels, has had a previous lower gastrointestinal tract investigation (colonoscopy, flexible sigmoidoscopy, defecating proctogram, digital rectal examination, CT colon) in the past 2 years.

What does the study involve?
Patients who have been referred for anorectal physiology studies as part of standard care will be considered to participate in the study. These tests routinely include endoanal ultrasound, anorectal manometry, and rectal sensitivity testing using elastic balloon distension. Participants will additionally undergo the rectal barostat test. Each participant will be offered a rectal sensitivity testing questionnaire to be completed in reception following their appointment, and once each participant has completed the exit questionnaire they will exit the study.

What are the possible benefits and risks to participating?
Participants will receive the results of the rectal barostat test within their clinic report provided to their consultant.
There is a burden of additional time required from the patient, which is about 30 minutes additional to their standard anorectal physiology appointment time. To minimise this burden, the additional barostat test will be performed at the same time as their standard care appointment, to avoid additional travel costs and time. The barostat test also carries a risk of pain, discomfort, bleeding, and perforation of the rectum (less than 1 in 1000), the same as standard rectal sensitivity testing using the elastic balloon, which the patients will also be undergoing as part of their standard anorectal physiology appointment. To minimise pain and discomfort, lubrication is used to insert the catheter and the participant is advised they can withdraw their consent at any point, and the test will be abandoned. To minimise the risk of bleeding, the test will be abandoned if there is any resistance during insertion of the catheter and participants are excluded from the study if they suffer from excessive or unexplained rectal bleeding. Any participants with risk factors of rectal perforation, such as previous pelvic surgery, pelvic radiotherapy, or inflammatory bowel disease are excluded from the study (according to exclusion criteria), and the barostat automatically deflates if the pressure of the rectal wall exceeds 80 mmHg.

Where is the study run from?
The study sponsor is Newcastle upon Tyne Hospitals NHS Foundation Trust. The study sites include the Royal Victoria Infirmary (Newcastle upon Tyne), and the University Hospital of North Durham (UK).

When is the study starting and how long is it expected to run for?
July 2023 to January 2026

Who is funding the study?
Newcastle upon Tyne Hospitals NHS Foundation Trust (UK)

Who is the main contact?
Dr Helen Parker, helen.parker38@nhs.net

Contact information

Type(s)
Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
331715

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 331715

Study information

Scientific Title
A feasibility study to assess rectal sensitivity using elastic balloon distension versus a rapid rectal barostat bag: is there an agreement in London Classification diagnoses?

Study objectives
This feasibility study will help investigate key variables required to inform a future definitive study, which will aim to determine whether patients receive a different diagnosis of rectal

sensitivity dependent upon the test used. Moreover, a definitive study will address the potential impact of rectal sensitivity testing methodologies on patient outcomes.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 14/02/2024, Dulwich Research Ethics Committee (Health Research Authority, 2nd Floor, 2 Redman Place, Stratford, London, E20 1JO, United Kingdom; +44 (0)207 104 8094; dulwich.rec@hra.nhs.uk), ref: 23/PR/1521

Study design
Feasibility randomized interventional multi-site study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Patients with bowel symptoms including symptoms of constipation or disorder of evacuation, faecal incontinence functional anorectal pain, faecal urgency and frequency of moving bowels, or a constant urge to move bowels

Interventions
Intervention: Rectal barostat test.
All participants will have the rectal barostat test, but the order of tests will be changed per patient to avoid bias on the order of tests influencing the results. Patients will either receive procedure A or procedure B:
Procedure A: Anorectal manometry, elastic balloon distension, endoanal ultrasound, rectal barostat
Procedure B: Rectal barostat, endoanal ultrasound, anorectal manometry, elastic balloon distension

The basic details (e.g. short title, study overview) of the study will be registered with the online randomisation software, Sealed Envelope (https://www.sealedenvelope.com/). The simple randomisation service for non-commercial clinical studies will be selected. At each site a secure NHS email address accessible only to the research team will be used to perform each randomisation. The unique participant randomisation number will be entered into the software. The software will then automatically randomise to procedure A or procedure B.

Intervention Type
Other

Primary outcome measure
1. The number of patients who were eligible to participate in the study per site from the start to the end of recruitment
2. The number of eligible patients who chose to participate in the study from the start to the end of recruitment
3. The number of participants that dropped out of the study from the start to the end of recruitment
4. The respective costs (£) of the rectal barostat test and the elastic balloon distension test per patient measured using a bottom-up approach (total staff time costed (£) per patient appointment including additional time (min) required for rectal barostat test + cost of rectal barostat bags (£) and (standard staff time (min) costed as allocated for standard patient appointment (£)+ No addition cost of the rectal barostat bags).
5. The time taken per participant for the elastic balloon distension test and the rectal barostat test to be completed in minutes/seconds, from the start of inflation to full deflation at the end of the test
6. Participant rectal barostat test acceptability measured by willingness to undergo the rectal barostat test again measured using the rectal sensitivity testing questionnaire at the end of the study

Secondary outcome measures
1. The London Classification diagnosis per patient as assessed by the elastic balloon distension test and the rectal barostat test at the end of the study
2. Rectal capacity in mL per participant as measured from the rectal barostat test at the end of the study
3. The percentage of rectal capacity for each sensory threshold (first sensation, normal urge, maximum tolerated volume) for all three rounds of sensation testing during the rectal barostat test at the end of the study
4. The difference in patient-reported comfort levels of the rectal barostat test and elastic balloon distension test measured using the rectal sensitivity testing questionnaire at the end of the study
5. Qualitative themes reported by study participants which may improve the patient experience of a future study. Assessed using open-ended questions from the rectal sensitivity questionnaire at the end of the study

Overall study start date
11/07/2023

Completion date
01/01/2026

Eligibility

Key inclusion criteria
1. Aged over 18 years
2. Aged under 90 years
3. Male or nonpregnant female
4. Meets 1 or more of the following indications for anorectal physiology investigations: symptoms of constipation or disorder of evacuation, faecal incontinence functional anorectal

pain, faecal urgency and frequency of moving bowels, constant urge to move bowels
5. Has had a previous lower gastrointestinal tract investigation (colonoscopy, flexible sigmoidoscopy, defecating proctogram, digital rectal examination, CT colon) in the past 2 years
6. Able to understand both written and verbal English

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
90 Years

Sex
Both

Target number of participants
30

Key exclusion criteria
1. Creutzfeldt-Jakob disease
2. Pregnancy
3. Previous rectal surgery
4. Previous pelvic radiotherapy
5. Haemorrhoid banding in past 2 weeks
6. Haemorrhoidectomy in past 10 weeks
7. Reporting of change of bowel habits, rectal bleeding, or weight loss with no endoscopic investigations performed since symptoms commenced
8. History of inflammatory bowel disease
9. History of colorectal or anal cancer
10. Lack of capacity to consent
11. Over 90 years old
12. Under 18 years old

Date of first enrolment
29/04/2024

Date of final enrolment
01/01/2026

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The Royal Victoria Infirmary and Associated Hospitals NHS Trust
Queen Victoria Road
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United Kingdom
NE1 4LP

Study participating centre
University Hospital of North Durham Cdc
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Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust

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Newcastle Joint Research Office, Regent Point
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NE3 3HD
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Sponsor type
Hospital/treatment centre

Website
http://www.newcastle-hospitals.org.uk/

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Newcastle upon Tyne Hospitals NHS Foundation Trust

Alternative Name(s)
Newcastle upon Tyne Hospitals NHS Trust

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The results of the study are intended to be disseminated via a poster, which will be submitted for conferences including the British Society of Gastroenterology (BSG), and the United European Gastroenterology (UEG) annual conferences. The research also be circulated across the Association of Gastrointestinal Physiologists via the newsletter NewWave, and written with the intent to publish to open-access peer-reviewed journals, to contribute to scientific and clinical communities.

Intention to publish date
01/07/2026

Individual participant data (IPD) sharing plan
The datasets generated during the current study are not expected to be made available publicly due to containing private and confidential patient data. However, the results will be shared with each participant's individual consultant.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.3	01/02/2024	24/02/2025	No	Yes
Protocol file		16/02/2024	24/02/2025	No	No