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Location of lesions responsible for blood loss in the GI tract

Submission date 28/01/2019	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 31/01/2019	**Overall study status** Completed	
Last Edited 03/12/2024	**Condition category** Digestive System	

Plain English summary of protocol

Background and study aims
Iron deficiency anaemia affects 2-5% of the adult population and accounts for between 4-13% of gastroenterology referrals as GI blood loss is considered the commonest cause in men and non-menstruating women. Single-visit upper and lower endoscopic investigation is recommended. Capsule endoscopy is the accepted gold standard for small bowel investigation and is extremely well tolerated. How often the small bowel is responsible for blood loss is unknown and probably underestimated. This study aims to assess the prevalence of lesions in the entire gastrointestinal tract by endoscopy in patients with iron deficiency anaemia.

Who can participate?
Patients aged 18 to 80 who have been referred for conventional upper and lower GI investigation to investigate their iron deficiency anaemia

What does the study involve?
Participants receive two sachets of polyethylene glycol the evening before the procedure as per normal small bowel endoscopy. Before the procedure height, weight and waist/hip circumference are measured. Participants undergo a magnetically assisted capsule endoscopy procedure to examine the upper GI tract and the small bowel. The participant completes the pre-endoscopy section of the participant questionnaire before, and the post-endoscopy section after the procedure. The same procedure is also followed for the gastroscopy element of the study.

What are the possible benefits and risks of participating?
The study itself carries minimal risk. Capsule endoscopy has traditionally been used to investigate diseases of the small bowel, which can cause the small bowel to be narrowed and prevent the capsule from passing through in about 1 in 200 cases. Therefore to ensure this risk is accounted for participants will be asked a number of questions to ensure that they have no history of small bowel diseases.

Where is the study run from?
1. Royal Hallamshire Hospital (UK)
2. Northern General Hospital (UK)

When is the study starting and how long is it expected to run for?
March 2018 to April 2023

Who is funding the study?
ANKON Technologies

Who is the main contact?
Prof. Mark McAlindon, mark.mcalindon@nhs.net

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CPMS 40125

Study information

Scientific Title
Location of lesions responsible for blood loss in the gastrointestinal (GI) tract

Acronym
BLITGIT

Study objectives

Is a magnetic controlled capsule endoscopy more effective than conventional gastroscopy when assessing the prevalence, nature and location of lesions in the gastrointestinal tract that may contribute to iron deficiency?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 14/09/2018, North West - Preston Research Ethics Committee, Barlow House, 3rd Floor, 4 Minshull Street, Manchester, M1 3DZ, Tel: +44 (0)207 104 8196, +44 (0)207 104 8234, Email: nrescommittee.northwest-preston@nhs.net, ref: 18/NW/0588

Study design
Non-randomized; Interventional; Design type: Diagnosis, Imaging

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Diagnostic

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
Gastrointestinal haemorrhage

Interventions
Patients who have been referred for conventional upper and lower GI investigation to investigate their iron deficiency anemia will be invited to undergo a magnetically assisted capsule endoscopy procedure to examine the upper GI tract and the small bowel.

Intervention Type
Other

Primary outcome measure
The prevalence and nature of lesions in the upper GI tract, small bowel and colon that cause Iron deficiency anaemia, measured using magnetically assisted capsule endoscopy; Timepoint(s): end of study assessment

Secondary outcome measures
1. The diagnostic yield of the upper GI magnetic controlled capsule endoscopy compared with conventional gastroscopy following both procedures

2. Patient-reported tolerance of capsule endoscopy and gastroscopy measured using a questionnaire following both procedures

Overall study start date
14/03/2018

Completion date
30/04/2023

Eligibility

Key inclusion criteria
1. Patients aged 18 years and over and up to but not exceeding 80 years
2. Patients presenting with IDA whom require gastroscopy and colonoscopy is indicated as per national guidelines

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
80 Years

Sex
Both

Target number of participants
Planned Sample Size: 100; UK Sample Size: 100

Total final enrolment
100

Key exclusion criteria
1. Patients under the age of 18 years
2. Patients over the age of 80 years
3. Active vomiting
4. Patients with a permanent pacemaker, implantable cardioverter-defibrillator or REVEAL device
5. Patients with any electronic/magnetic/mechanically controlled devices e.g. sacral nerve stimulators, bladder stimulators
6. Patients with dysphagia, odynophagia or known swallowing disorder
7. Patients with known Zenker’s diverticulum
8. Patients with suspected bowel obstruction or bowel perforation
9. Patients with prior bowel obstruction
10. Patients with gastroparesis or known gastric outlet obstruction
11. Patients with known Crohn’s disease

12. Patients who are taking daily non-steroidal anti-inflammatory drugs (excluding prophylactic doses of aspirin) for more than six months
13. Patients who have received abdominopelvic radiotherapy treatment
14. Patients with a history of GI tract surgery (Billroth I, Billroth II, Oesophagectomy, gastrectomy or bariatric procedure)
15. Patients that are pregnant or lactating
16. Patients with altered mental status that would limit their ability to swallow
17. Patients with allergy to conscious sedation or metoclopramide
18. Patients unwilling to swallow the capsule
19. Patients with known dementia affecting ability to consent
20. Patients who are unable to understand or speak English
21. Patients unable to provide written informed consent

Date of first enrolment
25/10/2018

Date of final enrolment
31/01/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Hallamshire Hospital
Glossop Road
Sheffield
United Kingdom
S10 2JF

Study participating centre
Northern General Hospital
Herries Road
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S5 7AU

Sponsor information

Organisation
Sheffield Teaching Hospital NHS Foundation Trust

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/018hjpz25

Funder(s)

Funder type
Industry

Funder Name
Shanghai Ankon Technologies Co Ltd

Results and Publications

Publication and dissemination plan
The trialists aim to present the results of these findings to nation and international conferences such as the British Society of Gastroenterology Annual meeting. They also hope to disseminate the findings by submitting results for publication in peer-reviewed journals.

Intention to publish date
01/01/2025

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No