

Location of lesions responsible for blood loss in the GI tract

Submission date 28/01/2019	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 31/01/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 03/12/2024	Condition category Digestive System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

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

Contact name
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Additional identifiers

Protocol serial number
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

Study type(s)

Diagnostic

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

80 years

Sex

All

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

United Kingdom

England

Study participating centre

Royal Hallamshire Hospital

Glossop Road

Sheffield

United Kingdom

S10 2JF

Study participating centre

Northern General Hospital

Herries Road

Sheffield

United Kingdom

S5 7AU

Sponsor information

Organisation

Sheffield Teaching Hospital NHS Foundation Trust

ROR

<https://ror.org/018hjpz25>

Funder(s)

Funder type

Industry

Funder Name

Shanghai Ankon Technologies Co Ltd

Results and Publications

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