ISRCTN12586238 https://doi.org/10.1186/ISRCTN12586238

Using a swallowable blood detection capsule to help triage patients presenting with symptoms of an upper gastrointestinal bleed

Submission date 13/03/2026	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 30/04/2026	**Overall study status** Ongoing	
Last Edited 30/04/2026	**Condition category** Digestive System	

Plain English summary of protocol

Background and study aims

This study tests whether a small swallowable capsule called PillSense can help doctors safely decide which patients with suspected bleeding from the upper gut can go home and have a camera test later, and who needs to stay in the hospital for urgent tests and treatment. A camera test refers to a thin flexible tube with a camera on the end that is inserted through the mouth under a sedative to determine the cause of bleeding from the upper gut that includes the gullet, stomach, and first part of the small intestines. This camera test is known as an endoscopy and can be completed as an inpatient or an outpatient. PillSense tells doctors whether blood is detected or not detected within only 10 minutes by transmitting data to a receiver that sits next to the participant. The capsule then passes naturally through the body, without causing harm, and is passed out in the stool. At present, all patients presenting with suspected bleeding from the upper gut are initially assessed by doctors who calculate their risk, using a special score, of developing problems from bleeding. This score is divided into low risk, moderate risk, or high risk. All patients at moderate or high risk are advised to be admitted to the hospital for more tests and an endoscopy. This study is seeing whether swallowing the PillSense capsule may help doctors safely discharge patients who have a negative test.

Who can participate?

Adult patients presenting to the hospital with symptoms of an upper gastrointestinal bleed.

What does the study involve?

Initially, a member of the research team will explain the study and answer any questions the participant may have. They will also show the participant a video of how the device works. If the participant agrees, they will be asked to sign a consent form. Once signed, investigators will ask the participant some questions about their symptoms, medical history, and medications. This is to ensure the participant is suitable to be part of the trial. Once investigators are happy the participant meets all criteria, they will be randomly allocated by a computer to one of two groups (like a coin toss). The study is not blinded, which means the participant and the investigators will know which group the participant was allocated to.

If the participant is randomised to standard care, they will be admitted to hospital and undergo further tests, including an endoscopy, which is standard for all patients with suspected bleeding from the upper gut in the UK. Investigators will keep an eye on what the doctors find during the endoscopy, and they will call the participant at 7 days, 14 days, and 30 days after admission to see how they are and determine what happened.

If the participant is randomised to PillSense, they will be given the PillSense capsule to swallow. Investigators will remain with them to give advice and guidance on how to swallow the capsule and what position to lie in. The participant will receive a result within 5–10 minutes. This will be displayed on the receiver as "Blood detected" or "No blood detected". The clinical team may use the result alongside the participant's symptoms, examination, and blood tests to decide whether the participant can safely go home and have their camera test later, or whether they should stay in hospital for urgent tests or treatment. If the participant is discharged, the team will organise an outpatient endoscopy within the next 3 to 5 days.
If the participant's condition changes, they become unwell, or they have more bleeding, then they will be advised to contact the research team, who will arrange for them to be admitted or may bring their endoscopy forward. If it is an emergency, the participant should always call 999 first, and then the participant or a relative should contact the investigators. Their safety always comes first.

The participant will receive a followup phone call at 7days, 14days, and 30days after admission to see how they are and to ensure the capsule has passed. They will need to check their stool each time they go to the toilet after swallowing the capsule to see if it has come out. If they have not seen the capsule, they must tell the investigators, who will organise an Xray of their tummy. The Xray will tell the researchers whether the capsule is still in their gut or has been safely passed.

What are the possible benefits and risks of participating?
There may not be a benefit directly. Possible benefits include a quicker decision about care and, if safe, the chance to go home sooner with a planned camera test at a later date. The results of this study will help improve how we assess and look after people with suspected bleeding from the upper gut.

Most people can swallow the PillSense capsule without difficulty. The pill is about the size of a large vitamin pill and should be swallowed with about 150 mL of water (1 small cup). Special swallowable capsules similar in size to PillSense are commonly used by bowel doctors to diagnose problems in the gut. The use of these capsules has helped us understand the risks associated with PillSense, which are uncommon and, in some cases, very rare. The main risks include:
• Sore throat
• Feeling sick
• Tummy discomfort
• Capsule retention (i.e. the capsule does not pass naturally): this occurs in around two people out of 100 who swallow a capsule device. If this occurs, it may need to be removed by an endoscopy, colonoscopy or surgery.
• Aspiration at the time of swallowing (i.e. breathing the capsule into the airway): this is very rare and occurs in around one person out of 1000 who swallows a capsule device.
• Bowel blockage or tear: this is a very rare problem that can occur when the capsule is retained and not removed.

There is also a small chance the test could be wrong. For example, saying "No blood detected" when there is some present within the stomach or upper gut. When PillSense says "No blood

detected," it's right about 98% of the time. This means out of 100 people with the "No blood detected" result, about 98 truly have no blood in the stomach and about 2 might still have some bleeding that wasn't picked up. It is important to remember that PillSense is an extra test to support doctors in making decisions and it does not replace their medical judgment or the planned endoscopy.
If there is concern, or participants have ongoing bleeding/symptoms, the team will consider this and arrange an admission to the hospital and/or endoscopy if needed.

Where is the study run from?
University College London Hospital
Southampton General Hospital

When is the study starting and how long is it expected to run for?
The study is expected to start in April 2026 and will run for approximately 1 year.

Who is funding the study?
The maker of the swallowable capsule: Enterasense.

Who is the main contact?
Dr Rehan Haidry, Haidryr@ccf.org
Dr Benjamin Norton, benjamin.norton@nhs.net

Contact information

Type(s)
Principal investigator

Contact name
Dr Tareq El Menabawey

Contact details
University College London Hospital
London
United Kingdom
NW1 2BU
+44 20 3456 7890
telmenabawey@nhs.net

Type(s)
Public, Scientific

Contact name
Dr Benjamin Norton

ORCID ID
https://orcid.org/0000-0003-2058-3162

Contact details
University College London Hospital
London
United Kingdom

NW1 2BU
+44 20 3456 7890
benjamin.norton@nhs.net

Additional identifiers

Integrated Research Application System (IRAS)
365163

Study information

Scientific Title
Pillsense system for the RIsk stratification Of suspected upper gastRointestinal bleeding to Improve the Triage of patIentS at modErate-risk: a randomised controlled trial

Acronym
PRIORITISE

Study objectives
Among patient presenting with features compatible with upper gastrointestinal bleeding (coffee-ground vomiting and/or melaena), and in the absence of haemodynamic instability or active bleeding (e.g. witnessed haematemesis), we aim
to use the PillSense system in those at moderate risk (based on a Glasgow-Blatchford score of 2-5) to determine whether they should be triaged for further management including endoscopy as an inpatient or outpatient. We hypothesise that this will increase the ability to safely discharge patients without blood within the upper gastrointestinal tract for early outpatient investigation, and therefore, prevent unnecessary hospital admissions.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 11/03/2026, North West - Greater Manchester South Research Ethics Committee (2 Redman Place, Stratford, E20 1JQ, United Kingdom; +44 2071048014; gmsouth.rec@hra.nhs.uk), ref: 25/NW/0366

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Parallel

Purpose
Diagnostic, Pathway prioritisation

Study type(s)

Health condition(s) or problem(s) studied
Upper gastrointestinal bleeding

Interventions
The PillSense system refers to an ingestible capsule designed to detect blood in the stomach and transmit real-time data to an external receiver. The PillSense System consists of two main components:
1. An ingestible capsule: A non-invasive, single-use device designed to detect blood in the stomach (dimensions: 11×27 mm).
2. An external receiver: A device that receives and displays real-time data transmitted from the capsule.

The PillSense System is designed to complement standard care by providing clinicians with critical information regarding the presence of blood in the stomach. This information can have significant implications for patient care and outcomes, clinical resource utilisation, and healthcare costs. The PillSense system could aid the diagnosis of upper gastrointestinal bleeding and contribute to more efficient resource allocation and improved patient care through the emergency setting.

Patients presenting with a suspected upper gastrointestinal bleed who are deemed at moderate risk based on the Glasgow-Blatchford score will be randomised 1:1 to receive PillSense or standard of care using a central web-based system with concealed allocation. Investigators and participants will be unblinded to the group allocation. If participants have been allocated to receive PillSense, they will proceed with the administration of the capsule. Participants randomised to standard of care or PillSense with a positive (“Blood detected”) result will be advised to undergo an inpatient endoscopy within 24-hours of admission according to standard practice for the management of upper gastrointestinal bleeding. All procedures will be completed according to standard operating procedures at each site. Participants randomised to PillSense with a negative (“Blood not detected”) result will be discharged and undergo an outpatient endoscopy within 5-days of the index presentation according to the standard operating procedure at each site. All participants randomised will undergo a remote, phone-call, follow-up at 7-days (+/-1), 14-days (+/- 3), and 30-days (+/- 5) after the date of presentation.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
PillSense

Primary outcome(s)
1. Safe discharge rate measured using Safe discharge rate of patients from the emergency department (ED) or medical assessment unit (MAU) with a stable upper gastrointestinal bleed

(UGIB) and Glasgow-Blatchford Score (GBS) between 2-5 who can be triaged home after a negative PillSense without readmission within 5-days. at 30-days

Key secondary outcome(s))

1. Incidence of upper gastrointestinal bleeding and associated Glasgow-Blatchford Score (GBS) measured using Total number of patients admitted with upper gastrointestinal bleeding and their corresponding GBS score during the trial recruitment period at During the recruitment period (i.e., while the study is enrolling participants)

2. Rate of 30-day rebleeding measured using Proportion of patients experiencing clinically significant recurrent upper gastrointestinal bleeding (as defined by the need for a red blood cell transfusion, repeat gastroscopy, need for radiological or surgical intervention, melaena after stool normalisation in colour, haemoglobin decrease ≥20g/L from discharge haemoglobin) within 30 days of index presentation at Within 30 days of index presentation

3. Rate of readmissions after negative PillSense with suspected gastrointestinal bleeding measured using Proportion of patients with a “No Blood Detected” PillSense result who are readmitted with suspected upper gastrointestinal bleeding prior to planned outpatient endoscopy (within 5-days). Criteria based on presenting complaint/clinician impression including: haematemesis, melaena, or unexplained anaemia with possible upper gastrointestinal bleeding at Within 5 days of index presentation / before planned outpatient endoscopy

4. Rate of readmissions after negative PillSense with objective gastrointestinal bleeding: measured using Proportion of patients with a “No Blood Detected” PillSense result who are readmitted with objective upper gastrointestinal bleeding prior to planned outpatient endoscopy (within 5-days) based on criteria 2 “Rate of 30-day rebleeding” at Within 5 days of index presentation / before planned outpatient endoscopy

5. Proportion of patients transitioning to rescue pathway measured using Proportion of patients randomised to PillSense who subsequently transition to the rescue pathway, with and without a PillSense result, due to haemodynamic instability or at the discretion of the investigator /treating clinician at During the index care episode (from ED presentation until discharge or pathway completion)

6. Time to outpatient endoscopy measured using Average number of days from index emergency department (ED) presentation to completion of outpatient diagnostic endoscopy at From index ED presentation until outpatient endoscopy is performed (typically within the planned 5-day outpatient pathway)

7. Time to inpatient endoscopy measured using Average time (hours) from ED arrival to inpatient endoscopy for patients managed as inpatients at From ED arrival to inpatient endoscopy during the index admission

8. Inpatient stay measured using Average duration of hospital admission (hours, days) from index ED arrival to discharge at From ED arrival to hospital discharge during the index admission

9. Emergency department stay measured using Average duration (mins, hours) from ED arrival to ED discharge or transfer to different department (e.g. medical assessment unit or same day emergency care) at From ED arrival to ED discharge or transfer

10. Time to emergency department discharge measured using Average time (mins, hours) from ED arrival to discharge for patients discharged directly from ED or medical assessment unit at From ED arrival to discharge from ED or MAU

11. Rate of 30-day mortality measured using Overall and UGIB-specific 30-day mortality at Within 30 days of index presentation

12. Adverse events measured using overall safety as reported by the rate of 30-day adverse events, serious adverse events, device deficiency, and device-related serious adverse events at Within 30 days of index presentation

13. Device accuracy measured using the specificity, sensitivity, positive predictive value, and negative predictive value of the PillSense system at Index diagnostic episode (i.e., comparison of PillSense result with clinical/endoscopic confirmation during the initial care pathway)

14. Patient satisfaction measured using Average scores using a bespoke patient and pathway satisfaction score for patients admitted for inpatient investigation, patients with a positive PillSense test and patients with a negative PillSense test at At completion of the care pathway (typically at discharge or shortly after investigation completion)

Completion date
31/05/2027

Eligibility

Key inclusion criteria
1. Adults aged ≥ 18 and < 85 years old
2. Presented to Emergency Department with symptoms of acute overt upper gastrointestinal bleeding such as coffee ground vomiting, haematemesis, or melaena*
3. Glasgow-Blatchford score of 2-5 on presentation
4. Patients who are willing and able to comply with the study protocol (including undergoing endoscopy).
5. Willing and able to give written informed consent**
*The presence of witnessed haematemesis within the department on arrival/admission will be an exclusion criterion.
**The use of a formal translator will be accepted

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
84 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Haemodynamic instability (systolic blood pressure ≤100 mmHg or heart rate ≥100 bpm)*
2. Clear need for urgent endoscopy or surgery as determined by the treating physician
3. Need for red blood cell transfusion
4. Active fresh haematemesis or haematochezia
5. The presence of any condition that would be a contraindication to the use of the ingestible PillSense Capsule:
5.1. Known or suspected gastrointestinal strictures
5.2. Dysphagia or odynophagia
5.3. History of achalasia or oesophageal dysmotility
5.4. History of gastroparesis
5.5. Zenker's diverticulum
5.6. Active Crohn's disease
5.7. Recent gastrointestinal surgery (within 6 months)
5.8. Suspected ileus or bowel obstruction
6. Known liver disease with advanced fibrosis/cirrhosis
7. Known history of oesophageal or gastric varices
8. Known upper gastrointestinal pathology that may predispose to bleeding, which has been diagnosed (e.g. ulcer) or treated (e.g. endoscopic submucosal dissection) within the last three months
9. Suspicion of an obstructing gastrointestinal tumour
10. Currently pregnant or breastfeeding, or intend to become pregnant during the investigation
11. Planned MRI within the next 30-days, which cannot be delayed
12. Presence of an implantable electrical device (e.g. cardiac, deep brain stimulator)
13. Unable to take anti-secretory medication (e.g. PPI or HR2A)
14. Use of medication prior to admission to stimulate gastric motility (e.g. prucalopride, domperidone, metoclopramide)
15. Altered mental status precluding informed consent
16. Use of dual anti-platelet therapy
17. Use of a direct oral anticoagulant with at least one anti-platelet agent
18. Myocardial infarction and/or percutaneous coronary intervention within the last 12 months
19. Any other mental or physical condition which, in the opinion of the investigator, makes the subject a poor candidate for clinical-trial participation
20. Any participant currently enrolled in another study investigating a medical device or investigational medicinal product (IMP).
*Confirmed on two assessments at least 15 minutes

Date of first enrolment
30/04/2026

Date of final enrolment
30/04/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University College London Hospitals NHS Foundation Trust
250 Euston Road
London
England
NW1 2PG

Study participating centre
Southampton
Southampton General Hospital
Tremona Road
Southampton
England
SO16 6YD

Sponsor information

Organisation
Enterasense Limited

Funder(s)

Funder type

Funder Name
Enterasense Limited

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available