

# A study on complete vs. incomplete small bowel examination using single-balloon enteroscopy in obscure gastrointestinal bleeding

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| <b>Submission date</b><br>04/04/2025   | <b>Recruitment status</b><br>No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol                       |
| <b>Registration date</b><br>10/04/2025 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                                  |
| <b>Last Edited</b><br>14/04/2025       | <b>Condition category</b><br>Digestive System     | <input type="checkbox"/> Individual participant data<br><input checked="" type="checkbox"/> Record updated in last year |

## Plain English summary of protocol

### Background and study aims

Obscure gastrointestinal bleeding (OGIB), accounting for about 5% of all gastrointestinal bleeding cases, often originates in the small intestine. Single-balloon enteroscopy (SBE) has recently been introduced as a diagnostic and therapeutic tool for OGIB but has a lower rate of complete small bowel examination. It remains unclear whether complete enteroscopy with SBE leads to better clinical outcomes. Some studies suggest that complete examinations significantly reduce rebleeding rates. Based on this, we hypothesize that complete SBE results in better clinical outcomes regarding rebleeding events compared to incomplete SBE. To investigate this, we conducted a multicenter observational study comparing rebleeding rates between patients undergoing complete and incomplete small bowel examination with SBE, aiming to evaluate the diagnostic value and clinical impact of complete enteroscopy in OGIB management.

### Who can participate?

Patients who are undergoing single-balloon enteroscopy for obscure gastrointestinal bleeding.

### What does the study involve?

Before undergoing the single-balloon enteroscopy (SBE) procedure, patients receive standard bowel preparation with 3 liters of polyethylene glycol solution administered 8 hours prior to the procedure. SBE is performed under conscious sedation or general anesthesia by experienced endoscopists, each of whom has performed at least 50 SBE procedures. The SIF-Q260 enteroscope (Olympus, Tokyo, Japan) is used in all cases. Data on clinical presentation, diagnosis, and whether the SBE is classified as complete or incomplete are collected. Patients are then categorized into two groups: complete and incomplete SBE. They are followed for re-bleeding events, with data obtained from medical records and telephone interviews. Clinical presentation, diagnosis, and interventions at the time of re-bleeding are recorded and compared between the two groups.

### What are the possible benefits and risks of participating?

There are no direct benefits or risks to patients participating in this study, as all participants will

continue to receive the standard best care. However, this study may provide valuable information on the clinical impact of complete and incomplete SBE in patients with OGIB.

Where is the study run from?

1. The First Affiliated Hospital of Zhengzhou University, Zhengzhou, China
2. Henan Provincial People's Hospital, Zhengzhou, China
3. Qinghai Provincial People's Hospital, Xining, China

When is the study starting and how long is it expected to run for?  
November 2022 to April 2025

Who is funding the study?  
Investigator initiated and funded

Who is the main contact?  
Fangbin Zhang, MD, PhD, fcczhangfb@zzu.edu.cn

## Contact information

### Type(s)

Public, Scientific, Principal Investigator

### Contact name

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## Additional identifiers

### EudraCT/CTIS number

Nil known

### IRAS number

### ClinicalTrials.gov number

Nil known

### Secondary identifying numbers

Nil known

## Study information

**Scientific Title**

Clinical outcomes of complete versus incomplete small bowel examination by single-balloon enteroscopy in obscure gastrointestinal bleeding: a prospective multicenter study

**Study objectives**

A complete small bowel examination leads to better clinical outcomes than an incomplete examination, including more accurate diagnosis and a lower risk of re-bleeding.

**Ethics approval required**

Ethics approval required

**Ethics approval(s)**

Approved 16/11/2022, Medical Ethics Committee of the First Affiliated Hospital of Zhengzhou University (No. 1 Jianshe East Road, Zhengzhou, 450052, China; +86 37166295219; yangzhgcp@163.com), ref: 2022-KY-1127

**Study design**

Multicenter observational study (retrospective analysis of prospectively collected data)

**Primary study design**

Observational

**Secondary study design**

Retrospective

**Study setting(s)**

Hospital, Medical and other records, Telephone

**Study type(s)**

Diagnostic

**Participant information sheet**

Not applicable (retrospective study)

**Health condition(s) or problem(s) studied**

Patients with obscure gastrointestinal bleeding are defined as those who have overt bleeding such as hematemesis, melena, or hematochezia, and have negative results on both upper endoscopy and colonoscopy.

**Interventions**

This study follows patients with obscure gastrointestinal bleeding who undergo either complete or incomplete small bowel examination using single-balloon enteroscopy between January 2016 and December 2024. Follow-up data on re-bleeding events are collected from medical records and telephone interviews. The aim is to compare the clinical outcomes between the two groups.

**Intervention Type**

Procedure/Surgery

**Primary outcome measure**

Re-bleeding events, defined as the recurrence of overt gastrointestinal bleeding such as hematemesis, melena, or hematochezia after the initial complete or incomplete single balloon enteroscopy. Clinical presentation, diagnosis, and interventions at the time of re-bleeding are collected from patient records

### **Secondary outcome measures**

Clinical findings and diagnoses from the initial single balloon enteroscopy, either complete or incomplete, are collected from patient records

### **Overall study start date**

01/11/2022

### **Completion date**

25/04/2025

## **Eligibility**

### **Key inclusion criteria**

1. A confirmed diagnosis of obscure gastrointestinal bleeding (OGIB)
2. Admission to one of the following institutions: The First Affiliated Hospital of Zhengzhou University, Henan Provincial People's Hospital, or Qinghai Provincial People's Hospital
3. Underwent single-balloon enteroscopy (SBE) between January 2016 and December 2024

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Lower age limit**

18 Years

### **Upper age limit**

80 Years

### **Sex**

Both

### **Target number of participants**

450

### **Key exclusion criteria**

1. Declined to participate in the follow-up
2. Were lost to follow-up during the study period

### **Date of first enrolment**

10/04/2025

### **Date of final enrolment**

20/04/2025

## Locations

### Countries of recruitment

China

### Study participating centre

**The First Affiliated Hospital of Zhengzhou University**

No. 1 Jianshe East Road

Zhengzhou

China

450052

### Study participating centre

**Henan Provincial People's Hospital**

No.7 Weiwu Road

Zhengzhou

China

450003

### Study participating centre

**Qinghai Provincial People's Hospital**

No.2 Gonghe Road

Xining

China

810007

## Sponsor information

### Organisation

The First Affiliated Hospital of Zhengzhou University

### Sponsor details

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**Sponsor type**

Hospital/treatment centre

**Funder(s)****Funder type**

Other

**Funder Name**

Investigator initiated and funded

**Results and Publications****Publication and dissemination plan**

Planned publication in a peer-reviewed journal

**Intention to publish date**

01/05/2025

**Individual participant data (IPD) sharing plan**

The current data sharing plans for this study are unknown and will be available at a later date

**IPD sharing plan summary**

Data sharing statement to be made available at a later date