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

Submission date 04/04/2025	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 10/04/2025	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 14/04/2025	**Condition category** Digestive System	[_] Individual participant data [X] 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

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Diagnostic

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(s)
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

Key secondary outcome(s))
Clinical findings and diagnoses from the initial single balloon enteroscopy, either complete or incomplete, are collected from patient records

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
80 years

Sex
All

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
Zhengzou
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450052

Study participating centre
Henan Provincial People's Hospital
No.7 Weiwu Road
Zhengzhou
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Study participating centre
Qinghai Provincial People's Hospital
No.2 Gonghe Road
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China
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Sponsor information

Organisation
The First Affiliated Hospital of Zhengzhou University

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes