PARTICIPANT INFORMATION SHEET AND INFORMED CONSENT FORM

Treatment Outcomes and Predictors After Endovascular Intervention for Portal Hypertension-Related Gastrointestinal Bleeding in Patients With Cirrhosis at the University Medical Center Ho Chi Minh City

TOPIC STUDY

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University Medical Center Ho Chi Minh City

Department of Gastroenterology

INFORMED CONSENT FORM

Study Title: Treatment Outcomes and Predictors After Endovascular Intervention for Portal Hypertension-Related Gastrointestinal Bleeding in Patients With Cirrhosis at the University Medical Center Ho Chi Minh City

Sponsor: None

Principal Investigator: Assoc. Professor. Thong Duy Vo, M.D. Ph.D.

Sub-Investigator: Qui Huu Nguyen, M.D.

Study Site/Institution: University Medical Center Ho Chi Minh City

I. STUDY INFORMATION

Purpose and Conduct of the Study

This study is conducted to describe the clinical and paraclinical characteristics and to evaluate treatment outcomes following endovascular intervention in patients with cirrhosis and gastrointestinal bleeding (GIB) due to portal hypertension (PH) at the University Medical Center Ho Chi Minh City.

The study also aims to identify certain factors associated with treatment outcomes following endovascular intervention.

The findings of this study may provide additional data regarding the effectiveness and safety of endovascular intervention techniques in the treatment of gastrointestinal bleeding due to portal hypertension.

The study will be conducted at the University Medical Center Ho Chi Minh City.

• Study period: From October 2026 to October 2028.

• Retrospective data: Medical records from January 2021 to September 2026.

• Prospective data: Collected from October 2026 to August 2028.

Inclusion Criteria

• Patients aged 18 years or older.

• Patients diagnosed with cirrhosis by the treating clinician based on clinical findings, laboratory investigations, imaging studies, or histopathology, if available.

• Patients diagnosed with gastrointestinal bleeding due to portal hypertension and treated with at least one endovascular intervention technique.

• Patients who provide informed consent to participate in the study (for the prospective study group).

Exclusion Criteria

• Pregnant women.

• Patients without cirrhosis or whose cirrhosis status cannot be clearly established.

• Patients with gastrointestinal bleeding unrelated to portal hypertension, such as peptic ulcer disease, gastrointestinal malignancy, Mallory–Weiss syndrome, etc., or patients in whom the cause of gastrointestinal bleeding cannot be clearly determined.

• Medical records lacking essential data required to assess the primary outcome.

Participants will not be required to undergo any additional procedures or investigations beyond those indicated as part of routine medical care.

The study team will only collect information obtained through interviews, medical records, and scheduled follow-up contacts by telephone.

Participation in this study is entirely voluntary. Participants have the right to refuse participation or withdraw from the study at any time without affecting their medical treatment.

Risks and inconveniences

This is an observational study and does not involve any therapeutic intervention or require additional tests or procedures beyond those routinely indicated as part of standard medical care. Therefore, participants will not be exposed to any additional medical risks as a result of participating in the study.

All data will be coded and kept confidential and will be used solely for research purposes.

Participation in the study will not alter the participant's treatment regimen, affect their rights to receive medical examination or treatment, or result in any additional administrative procedures for the patient.

Potential Benefits to Participants

Participants may receive more systematic monitoring and assessment of their medical condition during follow-up visits and may be contacted by telephone for follow-up during the 6-week period after hospital discharge.

However, participation in this study does not guarantee any direct therapeutic benefit to individual participants.

The results of this study may contribute to improving knowledge and the quality of care for patients with cirrhosis and gastrointestinal bleeding due to portal hypertension in the future.

The study does not provide any additional financial support or payment.

There will be no reimbursement for transportation, living expenses, or loss of income. Participants will not incur any additional costs beyond the costs of medical examination and treatment routinely charged in accordance with applicable regulations.

Payment and Method of Payment

Not applicable, as there is no payment to participants for participation in this study.

Compensation/Treatment for Study-related Injury

This study does not involve therapeutic intervention and does not require any additional procedures or tests beyond routine medical care. Therefore, study-related injury or harm is not anticipated.

If a health problem occurs and is determined to be directly related to a study activity, the participant will be assessed and managed in accordance with the hospital's professional medical regulations.

The study does not require any changes to the participant's treatment regimen or any special intervention. Therefore, choosing not to participate in the study or deciding not to continue participation will not affect the participant's health status.

Patients will continue to receive treatment in accordance with the hospital's standard clinical care procedures.

Contact Information

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Voluntary Participation

Participants have the right to make their own decision regarding participation and will not be coerced into participating.

Participants may withdraw from the study at any time without affecting the medical treatment or care to which they are entitled.

For individuals who are minors, have intellectual impairment, or lack decision-making capacity, informed consent will be obtained from their legally authorized representative.

CONFIDENTIALITY

The measures used to maintain and ensure the confidentiality of records relating to study participants shall be clearly described.

II. INFORMED CONSENT

I have read and understood the information provided above. I have had the opportunity to consider and ask questions about the information concerning this study.

I have spoken directly with the investigator and have received satisfactory answers to all of my questions.

I have received a copy of the Participant Information Sheet and Informed Consent Form for this study.

I voluntarily agree to participate in this study.

Participant's Signature

Full name: _____

Signature: _____

Date: _____

Signature of Witness or Legally Authorized Representative (if applicable)

Full name: _____

Signature: _____

Date: _____

Signature of Investigator/Person Obtaining Informed Consent

I, the undersigned, confirm that the patient/research participant who has signed this informed consent form has read the entire Participant Information Sheet above.

I confirm that the information has been thoroughly explained to the patient/participant and that he/she has clearly understood the nature, risks, and benefits of participating in this study.

Full name: _____

Signature: _____

Date: _____