University Hospitals Plymouth NHS Trust

UK Interventional Radiology Trainee Research Collaborative

British Society of Interventional Radiology

Mortality **A**fter lower **GI** bleed **C**atheter **Embo**lisation (MAGIC-Embo)

A multi-centre retrospective observational study investigating outcomes after emergency transcatheter arterial embolisation for acute non-variceal lower GI bleeding

Version 1.0: 26th November 2025

IRAS Number: **351622**

REC Reference: **XXX**

SPONSORS Number: **25RAD254**

Clinical Trial Registration: **XXX**

Put people first
Take ownership
Respect others
Be positive
Listen, learn, improve

This protocol describes the study and provides information about procedures for entering participants. Every care was taken in its drafting, but corrections or amendments may be necessary. These will be circulated to investigators in the study. Problems relating to this study should be referred, in the first instance, to the Chief Investigator.

This study will adhere to the principles outlined in the NHS UK Policy Framework for Health and Social Care Research (2017). It will be conducted in compliance with the protocol, the Data Protection Act (2018) and other regulatory requirements as appropriate

CONTENTS

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor.

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

Chief Investigator:		
Signature:		Date: 26/11/2025
Name:	Dr Deevia Kotecha	
For and on behalf of the Study Sponsor:		
Signature:	Electronic Signature	Date: Signature Date
Name:	.....	
Position:	.....	

KEY CONTACTS

Chief Investigator:	Dr Deevia Kotecha – Interventional Radiology Registrar and Honorary Research Fellow, University Hospital Plymouth NHS Trust
Co-investigators:	Miss Noemi Cinti, Foundation Year 1 Doctor, The Royal Wolverhampton NHS Trust, UK Dr Indrajeet Mandal, Interventional Radiology Registrar, Oxford Deanery, UK Dr Ganesh Vigneswaran, Consultant Vascular Interventional Radiologist Dr Raghuram Lakshminarayan, Consultant Vascular Interventional Radiologist, Hull University Teaching Hospitals, UK Dr Paul Jenkins, Consultant Vascular Interventional Radiologist, University Hospitals Plymouth NHS Trust, Plymouth, UK
Sponsor:	**University Hospitals Plymouth NHS Trust**
Funder(s):	**British Society of Interventional Radiology (BSIR)**

GLOSSARY OF ABBREVIATIONS

BSIR	British Society of Interventional Radiology
CI	Chief Investigator
CT	Computed Tomography
CTA	Computed Tomography Angiogram
DGH	District General Hospital
DSA	Digital Subtraction Angiography
ED	Emergency department
GA	General anaesthesia
GI	Gastrointestinal
Hb	Haemoglobin
INR	International Normalised Ratio
IR	Interventional Radiology
LA	Local anaesthesia
NIHR	National Institute for Health and Care Research
NHS	National Health Service
PI	Principal Investigator
RCR	Royal College of Radiologists
SOP	Standard Operating Procedure
UNITE	UK National Interventional Radiology Trainee Research Collaborative

KEY WORDS

Angiography

Embolisation

GI bleed

Haemorrhage

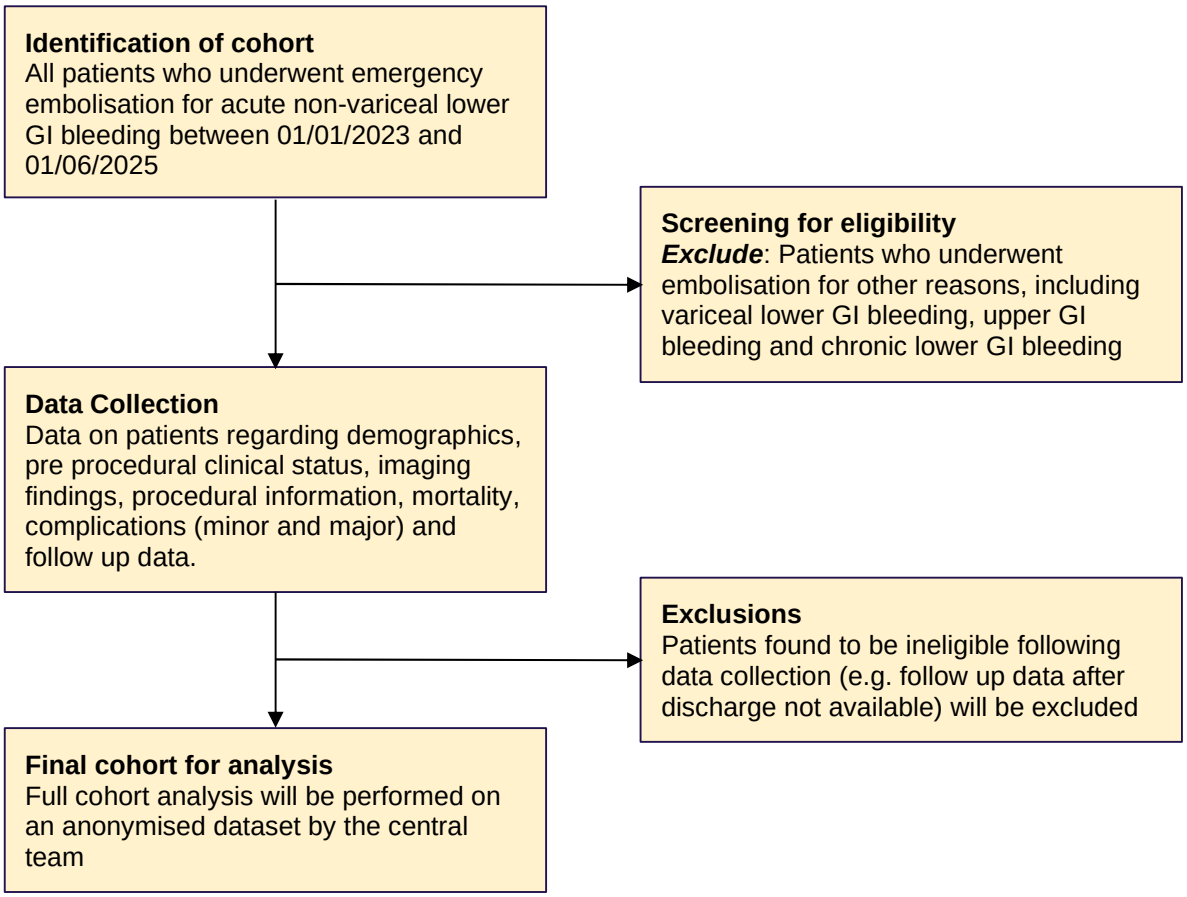
Intervention

STUDY SUMMARY

Study Title	**M**ortality **A**fter **GI** bleed **C**atheter **Embo**lisation (MAGIC-Embo)
Study Design	Multicentre retrospective study
Study Participants	All patients who underwent angiography +/- embolisation for acute non-variceal lower GI haemorrhage.
Primary Objectives	• To establish the rate of mortality, rebleeding, re-intervention, embolisation failure and complications after embolisation for acute non-variceal lower GI bleeding
Secondary Objectives	• To determine variations in embolisation technique / agents used and assess whether these impact on technical and clinical outcome • To determine clinical features that predict a successful or unsuccessful embolisation procedure • To determine whether CT imaging features correlate with DSA findings • To determine whether clinical variables correlate with DSA findings
Eligibility Criteria	**Inclusion Criteria:** 1. Adult patients (aged 16 years or more) undergoing emergency embolisation for acute non-variceal lower GI bleeding 2. Date of procedure from 01/01/2023 to 01/06/2025 **Exclusion Criteria:** 1. Patients who underwent embolisation for variceal GI bleeding 2. Patients who underwent embolisation for upper GI bleeding 3. Patients who underwent embolisation for chronic gastrointestinal bleeding (defined as >30 days)
Planned Sample Size	30 local patients with contributions from other centres in the UK (minimum 800 patients expected)
Follow-up Duration	6 months from date of procedure or date of death, whichever is sooner

Planned Study Period	12 months 15/11/2025 and 14/11/2026

STUDY FLOW CHART



1. Introduction

1.1 Lay Summary

Bleeding from the gut can be life-threatening and can lead to hospitalisation, serious complications or death. Traditionally, surgery has been used to stop the bleeding, but this can carry significant risks.

Interventional radiology plays an important role in diagnosis and treatment. Small catheters can be placed by pinhole techniques and directed by X-rays to examine the blood vessels and find the source of bleeding. If a bleeding source is identified, an embolisation procedure can be performed to block the affected blood vessel. During embolisation, the doctor can inject small particles or coils into the artery through the catheter to stop blood flow to the bleeding area while allowing normal blood flow to the rest of the body. This is a quick and effective procedure and is now widely accepted as an effective way to manage life threatening bleeding, avoiding major surgery.

We will be looking back in time to identify patients who underwent embolisation for bleeding from the back passage. The aim is to analyse the current practice of emergency embolisation for this type of bleeding. We will assess predictors of successful embolisation and assess whether timing affects outcomes. The findings could help guide hospital policy and improve emergency management.

1.2 Background

Acute non-variceal GI bleeding is a common surgical emergency associated with high rates of hospitalisation, as well as a mortality rate ranging from 2 to 10% (1). Management of lower GI bleeding is complex, requiring a multi-specialty approach. In clinically unstable patients with signs of active bleeding, focus is on early resuscitation, timely investigation to localise source of bleeding with CT angiography and appropriate intervention to stop bleeding e.g. surgical intervention or trans-arterial catheter embolisation.

Different risk scores exist for early identification and prognostication of patients for whom specific clinical management would be appropriate. In clinical practice, the Oakland and Strate scores are risk assessment tools used in the context of lower GI bleeding. The Oakland score can be useful in identifying those patients suitable for outpatient management who are at low risk of adverse outcomes. The BLEED, NOBLADS, Strate and Segupta scores were developed to predict severe bleeding and death (2). At present, there are no such risk scores to guide patient selection for emergency embolisation. Particularly in patients with high-risk features for re-bleeding and/or mortality, selective transcatheter arterial embolisation represents a valid and safe alternative to surgery, leading to high rates of favourable clinical outcomes in lower GI bleeding (3).

Trans-catheter arterial embolisation can also be performed empirically in patients with active bleeding clinically and an identified bleeding point on CT angiography, but no clearly identifiable source of bleeding on catheter angiography (4). Empirical preventative approaches are not widely explored in the literature for lower GI bleeding; this is likely due to perceived ischaemic risk and a higher conceptual risk of complications, limiting its current indication to acute and complex cases with fewer management options (4,5).

Whilst embolisation has proven to be a valid intervention, risk assessment specifically tailored for embolisation patients is less developed. Whilst clear pathways and scoring systems exist for endoscopic decision-making, no equivalent risk stratification tools exist to guide patient selection for emergency embolisation. This represents a significant clinical gap, especially in cases where endoscopy is unsuccessful or unfeasible, and embolisation may be lifesaving. Developing tools using insight into mortality and rebleeding following embolisation could further improve clinical outcomes by empowering clinicians to be able to make informed decisions and select the right procedure for the right patient at the right time.

1.3 Rationale for Study

The aim is to analyse the current practice of emergency embolisation for lower GI bleeding. We will assess predictors of lower GI embolisation and assess whether timing affects outcomes. The findings could help guide hospital policy and improve emergency management.

1.4 Participant and Public Involvement

To ensure our research is comprehensive and patient-centred, we have planned a Patient and Public Involvement (PPI) component. We have established a patient public involvement group in collaboration with the Guts UK Charity. Whilst surgery and endoscopy might be more familiar to patients, embolisation as an option is less well appreciated. This project provides an opportunity to widen patient perspectives on this life-saving therapy, incorporating and sharing the views of the community affected by lower GI bleeding. Involvement would ensure patients are educated and empowered about access to this treatment approach.

Detailed patient feedback has been sought from two patients so far. Both patients felt the project is essential, and an opportunity to make others aware of the seriousness of this life-threatening condition and what treatment patients are likely to receive.

The study protocol is very comprehensive and it has answered a number of questions regarding the bleeding and emergency surgery, which we understand saved my life.

We will organise a meeting with the PPI group once the project results are finalised. In this meeting, we will share with them our findings and the ways in which their contributions have shaped this research project. Patients will have the opportunity to voice their opinions, and these will be considered during the development of a scientific paper manuscript. We aim to publish the findings of this research project in a scientific paper, and patients will be acknowledged as part of the submission.

2. STUDY OBJECTIVES

2.1 Primary objectives

- To establish the rate of rebleeding, re-intervention, embolisation failure and complications after embolisation for acute non-variceal lower GI bleeding

2.2 Secondary objectives

- To determine variations in embolisation technique / agents used and assess whether these impact on technical and clinical outcome
- To determine clinical features that predict a successful or unsuccessful embolisation procedure
- To determine whether CT imaging features correlate with DSA findings
- To determine whether clinical variables correlate with DSA findings

3. STUDY DESIGN AND METHODS

3.1 Research Window

This national retrospective observational study will investigate the emergency embolisation for acute non-variceal lower GI bleeding (defined as distal to the ligament of Treitz). This will include data from patients undergoing the procedure in centres within the United Kingdom. The study period is 30 months from 01/01/2023 to 01/06/2025 which should allow for a large enough sample size of patients.

- Most large Interventional Radiology units would expect to perform around 15 embolisations per year. Therefore, with the multi-centre nature of this retrospective analysis, this should provide an adequate cohort for analysis.

4. STUDY PARTICIPANTS

4.1 Screening procedures

Centres will be identified using the UNITE network (https://www.unitecollaborative.com/) and the NIHR Research Delivery Network alongside the NIHR associate principal investigator

scheme. Interest in the project exists from a total of 25 centres across the UK already. UNITE has successfully performed and published multi-centre studies (MACAFI and CAASP studies) in up to 32 centres.

4.2 Inclusion criteria

All patients who underwent emergency embolisation for acute non-variceal lower GI bleeding between 01/01/2023 and 01/06/2025.

4.3 Exclusion criteria

Patients who underwent embolisation for other reasons, including variceal lower GI bleeding, upper GI bleeding and chronic lower GI bleeding (>30 days).

5. STUDY PROCEDURES AND INTERVENTIONS

5.1 Definition of End of Study

This is defined as the date of the last data submitted by the site. The sponsor will notify the REC, in writing, within 90 days of the end of the study.

6. STATISTICS

6.1 Sample Size

The primary objective of the study is to identify current practice as well as the rate of rebleeding and outcomes without a comparator, and therefore no minimum number of patients is required.

6.2 Data Analysis

Analysis of this data will be conducted, and the following results will be calculated, both overall and a subgroup analysis: mortality, rebleeding, length of stay, time to intervention. Additionally, predictors of rebleeding/mortality will also be calculated and the results of this will be used to form a prediction model to help guide clinical selection of patients for embolisation.

All statistical analysis will be performed using R. P values <0.05 will be considered significant.

For clinical characteristics with missing data greater than 10%, multiple imputation methods will be considered.

7. DATA MANAGEMENT AND DATA SHARING PLAN

To comply with the Data Protection legislation, information will be collected and used fairly, stored safely and not disclosed to any unauthorised person. This applies to both manual and electronically held data.

Results will be released to the individual participants but will not be made available outside of the research team.

7.1 Data Collection

Data will be collected by a named doctor as part of the IR trainee research collaborative (UNITE) or interventional radiology trainees, junior doctors and medical students at each participating centre and will be maintained on an anonymised (REDCap) database. They will be supervised by an Interventional Radiology Consultant who will be a permanent employee of that centre. This type of work is part of their expected role for the purposes of quality improvement and revalidation. Registrars will collect this data as part of their training time where there is a requirement to be involved in audit and research. Applicants from participating sites can register to be an Associate PI for this study as part of the NIHR Associate Principal Investigator Scheme.

All data will be anonymised prior to leaving the centre. All data will be collected using the purpose-built electronic database Research Electronic Data Capture (REDCap) platform, which is overseen by the University of Plymouth. No identifiable data (patient number, full name, date of birth) will be recorded or shared.

Data collected falls into the following categories (examples given after each category are not exhaustive – see Appendix 1):

- Participant ID number (pseudo-anonymised)
- Demographics: Age, gender, date of admission
- Comorbidities
- Pre-procedural imaging: Dates, modalities, diagnosis
- Treatments offered prior to procedure: Antibiotics, IV fluids, blood transfusion, endoscopy
- Procedure: Date, procedural findings
- Intraoperative complications
- Post-operative complications: Types, date of occurrence, treatment
- Follow up: readmissions, 30-day mortality, cause of death, further interventions

The patients will not be contacted at any point. At no point will the data be identifiable outside the site at which embolisation was performed. Only pseudonymised data will be sent to the central research team for analysis.

7.2 Collection of data and study materials

Data will be collected, analysed and held on secure Trust PC and on the purpose-built electronic database Research Electronic Data Capture (REDCap) platform overseen by the University of Plymouth.

7.3 Data storage and security

All data will be stored on a Trust computer in a password protected file with access only available by the local lead. Anonymised data only will be shared with the central team.

7.4 Archiving, preservation and curation

Archiving will be authorised by the Sponsor following submission of the end of study declaration. Upon completion of the study, study documents will be archived for a minimum of 5 years as per the participating Trust's Research Archiving SOP. Once the archiving retention period has been reached, the Sponsor will liaise with the CI regarding destruction.

8. ETHICAL AND REGULATORY COMPLIANCE

8.1 Ethical Approval and Registration

The retrospective observational study will be conducted in compliance with the principles of the ICH GCP guidelines and in accordance with all applicable regulatory guidance including, but not limited to the UK Policy Framework for Health and Social Care research.

IRAS and HRA ethical approval will be sought. No patient identifiable information will be stored by the central research team.

8.2 Ethics and HRA approval

The Chief Investigator will obtained approval from the Health Research Authority (HRA). The Investigator will ensure that this study is conducted in full conformity with relevant regulations and with the UK Policy Framework for Health and Social Care Research (2017), which have their basis in the Declaration of Helsinki.

8.3 Indemnity

This is an NHS-sponsored research study. If an individual suffers negligent harm as a result of participating in the study, NHS indemnity covers NHS staff and those people responsible for conducting the trial who have honorary contracts with the relevant NHS Trust. In the case of non-negligent harm, the NHS is unable to agree in advance to pay compensation, but an *ex-gratia* payment may be considered in the event of a claim.

8.4 Sponsor

UHP will act as the main sponsor for this study assuming overall responsibility for the initiation and management of the trial. Delegated responsibilities may be assigned to other relevant parties taking part in this study and appropriately documented.

8.5 Funding

A British Society of Interventional Radiology (BSIR) Research Bursary Grant and Royal College of Radiologists (RCR) Kodak Grant have been awarded for this study. The BSIR Research Committee has awarded £10,400. The RCR have awarded £43,077. When the final research is published, we will acknowledge BSIR's involvement in funding within any articles.

8.6 Monitoring

The study will be subject to monitoring by UHP under their remit as sponsor to ensure adherence to the UK Policy Framework for Health and Social Care Research (2017). All UHP studies will be initially monitored prior to Green Light being given. The subsequent level of monitoring will be determined by a risk assessment, or on a for cause basis. The study may also be audited/ inspected by regulatory bodies to ensure compliance with national regulations.

9. STUDY MANAGEMENT

The day-to-day management of the study will be co-ordinated through the research team.

10. Publication Policy

Final results of the study will be disseminated via presentations at appropriate scientific meetings and conferences and publication in appropriate peer-reviewed journals. Authorship will involve named individuals involved in study design and manuscript preparation with the UK IR Trainee Research group, with individuals collecting data at hospital sites being specifically named as collaborators.

A writing team, including those involved with the design, implementation and dissemination of the MAGIC-Embo study, and those contributing to data analysis will be responsible for both presentation(s) and publication(s). For both presentation(s) and publication(s) a collaborative authorship model will be used.

Criteria to qualify for collaborative authorship are defined as:

1. Had a significant role in the set up and management of the MAGIC-Embo study; including local registration, creation of a data collection team and engagement with UNITE to ensure timely upload of data

OR

2. Captured sufficient data to warrant authorship – this would be the equivalent of collecting data on at least 20 patients.

OR

3. (for local study leads) provide oversight and support as detailed in sections

AND

4. Review and approve any resultant manuscript(s) for submission to a peer-reviewed journal.

The corresponding author will take primary responsibility for communication with the journal throughout the submission process.

The anticipated number of team members per centre is 1 local study lead + 3 other team members (trainees, allied healthcare professionals, medical students).

The main line authorship will be determined according to the ICMJE recommendations. The top recruiting sites will be invited to contribute to the manuscript and will be named main line authors.

11. References

1. Mujtaba, S., Chawla, S., Massaad, J.F., 2020. Diagnosis and Management of Non-Variceal Gastrointestinal Hemorrhage: A Review of Current Guidelines and Future Perspectives. J Clin Med 9, 402.
2. Oakland K, Chadwick G, East JE, Guy R, Humphries A, Jairath V, McPherson S, Metzner M, Morris AJ, Murphy MF, Tham T, Uberoi R, Veitch AM, Wheeler J, Regan C, Hoare J. Diagnosis and management of acute lower gastrointestinal bleeding: guidelines from the British Society of Gastroenterology. Gut. 2019 May;68(5)
3. Lu, Y., Loffroy, R., Lau, J.Y.W., Barkun, A., 2014. Multidisciplinary management strategies for acute non-variceal upper gastrointestinal bleeding. British Journal of Surgery 101, e34–e50.
4. Ini', C., Distefano, G., Sanfilippo, F., Castiglione, D.G., Falsaperla, D., Giurazza, F., Mosconi, C., Tiralongo, F., Foti, P.V., Palmucci, S., Venturini, M., Basile, A., 2023. Embolization for acute nonvariceal bleeding of upper and lower gastrointestinal tract: a systematic review. CVIR Endovascular 6, 18.
5. Strate, L.L., Gralnek, I.M., 2016. ACG Clinical Guideline: Management of Patients With Acute Lower Gastrointestinal Bleeding. Official journal of the American College of Gastroenterology |ACG 111, 459.

12. Appendix

12.1 Appendix 1 - Data points to be collected

Patient demographics (age at presentation, gender, Charlson co-morbidity index score)

Basic Admission Clinical Information

- Mode of presentation (ED, existing inpatient, referral from district general hospital)
- Date of CT diagnosis
- Baseline bloods prior to admission for GI bleeding (if available)
    - Hb (g/L)
    - Urea
    - Creatinine
- Baseline bloods on day of CT angiography:
    - Hb (g/L)
    - Platelets
    - INR, aPTT
    - Urea
    - Creatinine
- First recorded vital signs on day of diagnosis (BP, HR)
- Anticoagulation (Y/N), If yes what agent and dose?
- History of previous clotting disorder (Y/N) if so what?
- Co-morbidities
- Charlson Co-morbiditiy index

Imaging Information

- Imaging diagnosis date and time
- Imaging modality first confirmed (Triple phase CT angiogram/ portal venous phase CT abdomen pelvis)
- Bleeding point identified on CTA (Y/N) and if yes where was the identified bleeding point on CT?
- Presumed cause of bleed
- CT features of bleed:
    - Extravasation (focal area of high-attenuation in the bowel lumen not present on pre-contrast or earlier phase imaging),
    - Sentinel clot (acutely clotted blood,which appears hyperattenuating and may be located closest to the bleeding site)
    - Change in size, attenuation, shape and location on later phase portal venous phase imaging.
- Specific branch
- SMA and IMA patency
- Did the CT show any signs of bowel ischaemia (Y/N)

IR Referral and Pre-operative Management Data

- Documented date and time of first discussion with IR
- Recent surgery prior to onset of bleeding? (Surgery within the preceding 30 days) - if yes what?
- Did the patient undergo endoscopic evaluation/ treatment before angiography (Y/N)
- Was there an initial conservative approach (clear documentation in notes to hold off embolisation) (Y/N) - how many days?
- Anaesthetics review pre-operatively (Y/N)
- Anaesthetist present during case (Y/N)
- Local anaesthesia/ Sedation / Spinal anaesthesia / General Anaesthesia
- Haemodynamic instability prior to procedure (defined as hypotension with systolic pressure <100 mmHg and heart rate >100 beats/min or clinical shock secondary to blood loss) (Y/N)
- Fluid resuscitation pre-operatively (Y/N) and how much
- Blood transfusion pre-operatively (Y/N) If no, was there any reason?
- How many units of RBC transfused?
- How many units of platelets transfused?
- Any additional factors e.g. FFP, cryo
- Was clotting corrected?
- Tranexamic acid administered prior?

Intra-procedural Data

- Date and time of angiogram (time when first image acquired)
- Access (femoral / radial) and max sheath size
- Digital Subtraction Angiography (DSA) bleeding point (Y/N)
- Additional DSA features of bleeding demonstrated? (e.g. vessel spasm, truncated vessel sign)
- If no bleeding point identified angiographically was empirical embolisation performed (Y/N)
- Provocative angiogram performed? (Y/N)
- Intraprocedural hyoscine butylbromide (buscopan) (Y/N)
- Artery(ies) embolised (jejunal branch, ileal branch, ileocolic artery, left colic artery, right colic artery, middle colic artery, sigmoid artery, marginal artery, superior rectal artery, middle rectal artery, inferior rectal artery)
- Proximal/distal portion of artery , branch
- Embolic material used (coils, plug, glue, gelfoam, particles, Onyx, other, multiple)
- More than one embolic agent used? (Y/N)
- Further details of embolic material e.g type of coil, coil size, number of coils, size of particles, embolic volume, dilution ratios
- Closure device used

Follow-up

- Intensive care unit (ICU) admission (Y/N)
- ICU length of stay
- 30 day mortality (Y/N)
- Complications
    - Minor complication: Bleeding from access site, pseudoaneurysm formation, abscess at access site
    - Major complication: Arterial dissection of target vessel, coil migration, intestinal ischaemia, lower GI tract perforation
    - If complication, what is the overall Clavien-Dindo grade?
        - **Grade 1:** Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic and radiological interventions
          (Acceptable therapeutic regimens are: drugs as anti-emetics, antipyretics, analgesicsm diuretics and electrolytes and physiotherapy)
        - **Grade 2:** Requiring pharmacological treatment with drugs other than such allowed for grade 1 complications. Blood transfusions, antibiotics and total parenteral nutrition are also included)
        - **Grade 3:** Requiring surgical, endoscopic or radiological intervention
            - Grade 3a: Intervention under regional/local anaesthesia
            - Grade 3b: Intervention under general anaesthesia
        - **Grade 4:** Life threatening complication requiring intensive care unit management
            - 4a: Single organ dysfunction
            - 4b: Multi-organ dysfunction
        - **Grade 5:** Patient death
    - If complication, what is the CIRSE Classification?
        - **Grade 1a:** Complication during the procedure which could be solved within the same session and intended procedure was completed; no additional therapy, no post-procedure sequelae, no deviation from the normal post-therapeutic course.
        - **Grade 1b:** Complication during the procedure which could be solved within the same session but the intended procedure had to be abandoned; no additional therapy, no post-procedure sequelae, no deviation from the normal post-therapeutic course
        - **Grade 2:** Prolonged observation including overnight stay (as a deviation from the normal post-therapeutic course < 48 h); no additional post-procedure therapy, no post-procedure sequelae
        - **Grade 3a:** Additional post-procedure therapy or prolonged hospital stay (> 48 h but < 2 weeks) required; no post-procedure sequelae
        - **Grade 3b:** Additional post-procedure therapy or prolonged hospital stay (> 2 weeks) required; no post-procedure sequelae
        - **Grade 4:** Complication causing a permanent mild sequelae (resuming work and independent living)

        - **Grade 5:** Complication causing a permanent severe sequelae (requiring ongoing assistance in daily life)
        - **Grade 6:** Death
- Clinically significant rebleeding within 30 days post-procedure (Y/N)
- If yes, how many hours/days from embolisation to rebleed
- Was repeat CT imaging performed within 30 days (Y/N)
    - If yes, further bleeding/bleeding point identified on CT? (Y/N)
    - If yes, what vessel ?
- Repeat intervention within 30 days (Y/N) - include date(s) and time(s) of intervention
- Did the patient undergo endoscopic evaluation/ treatment after angiography (Y/N)
- Did the patient undergo open surgery after angiography (Y/N)
- Did the patient undergo repeat angiography +/- embolisation (Y/N).
    - If yes, how many times?
    - If embolised:
        - Proximal/distal portion of artery/ branch
        - Embolic material used (coils, plug, glue, gelfoam, particles, Onyx, other, multiple)
        - Further details of embolic material e.g. coil size, size of particles
        - Closure device used
- 30 day, 90 day and 6 month mortality

12.2 Appendix 2 - Estimated Timelines

Estimated Timelines

December 2025: Completion of Protocol by UNITE and Ethics Submission

January 2026: Ethics Committee Recommendation

February 2026: National roll-out and site recruitment

March 2026: Local project registration / data collection

August 2026: Data collection period ends

September 2026: Data analysis begins (plus contingency time for additional data collection)

October 2026: Interim Lead Investigator meeting for resolution of discrepancies

November 2026: Review and synthesis of results

January 2027: Write up and manuscript preparation

February 2027: Dissemination by manuscript draft 1

April 2027: Manuscript submitted to peer reviewed journal

September 2027: CIRSE presentation

November 2027: BSIR presentation