

Causes and outcomes of internal bleeding in the digestive system

Submission date 31/08/2018	Recruitment status Recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 06/11/2018	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 07/07/2025	Condition category Digestive System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and aims

Internal bleeding from the stomach and the gut may show as vomiting up blood. It may also show as passing blood in the toilet. Sometimes you can see the blood clearly in the toilet, and sometimes it is there but it cannot be seen. This study aims to determine if this internal bleeding changes from year to year - whether it changes with age, smoking, and use of alcohol, and whether it changes with the use of certain drugs.

Who can participate:

Adults suffering from internal stomach or gut bleeding

What does the study involve?

There will be no direct participation from participants, as this study is a review of previous cases of internal bleeding (1996 to present) and new cases from now until 2026. Patient details will be kept confidential and anonymous. Records will be reviewed for changes in various factors over time, including patient demographics, other illness, causes and nature of bleeding, drugs taken and whether patients have had surgery, amongst various other factors.

What are the possible benefits and risks of participating?

The possible benefit of taking part in this study is that the results could improve future treatment of patients with internal bleeding, and this may help to train doctors. There are no known risks to participants taking part in this study, as it does not require direct participation.

Where is the study run from?

Gastroenterology Unit at University Hospital Crosshouse, Kilmarnock, Scotland (UK)

When is the study starting and how long is it expected to run for?

January 2002 to December 2026

Who is funding the study?

Gastroenterology Endowment Fund, University Hospital Crosshouse, NHS Ayrshire and Arran, Scotland (UK)

Who is the main contact?
Professor Ali S Taha
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Contact information

Type(s)
Scientific

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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
Assessments of epidemiology, aetiology, and outcomes of gastrointestinal bleeding

Study objectives
The epidemiology, aetiology, and outcomes of gastrointestinal bleeding continue to change as a reflection of the increasing use of both mucosal damaging and protective agents. Damaging agents include non-steroidal anti-inflammatory drugs, aspirin, old and new anti-thrombotic drugs given as part of cardio-vascular protective strategies. Mucosal protective drugs mainly include proton-pump inhibitors.

Ethics approval required
Old ethics approval format

Ethics approval(s)

These audit assessments have been approved by the Information Governance Office, on behalf of the Caldicott Guardian, NHS Ayrshire and Arran, Scotland. They do not require ethics approval due to their audit nature. The Manager of the West of Scotland Research Ethics Service had advised that "If the purpose of the study is more of a service evaluation, looking at outcomes, etc., then as audit/service evaluation we would not require ethical review. Consent is good to have but where you are not able to secure consent for retrospective data then access to the data should be appropriately controlled. If it is your own clinical data this is not usually an issue however anyone outside of the routine clinical care team should only access anonymised data. If you are getting data from outside of NHS Ayrshire and Arran then this would require PBPP approval. For the prospective cases you are looking to seek consent for the use of anonymised data which is best practice."

Study design

Current study design as of 11/12/2020:

Prospective and Retrospective observational epidemiology study - audit assessments of causes and outcomes of gastrointestinal bleeding over a 30-year period (1996-2026)

Previous study design:

Observational epidemiology study - audit assessments of causes and outcomes of gastrointestinal bleeding over a 30-year period (1996-2026)

Primary study design

Observational

Study type(s)

Other

Health condition(s) or problem(s) studied

Gastrointestinal bleeding

Interventions

Patients' details will be anonymised. From their medical records, the following will be analysed:

1. Demography
2. Coexisting conditions
3. Drug therapy
4. Nature of gastrointestinal bleeding (overt, obscure, etc)
5. Length of hospital stay
6. Causes of bleeding
7. Need for transfusion
8. Use of acid inhibitors
9. Need for surgery
10. Other complications of gastrointestinal bleeding
11. Re-bleeding
12. Factors that might help stop bleeding and prevent re-bleeding
12. All-cause mortality

Intervention Type

Other

Primary outcome(s)

Current primary outcome measure as of 11/12/2020:

Time trends of the following will be assessed through a review of patient medical records:

1. Demography
2. Coexisting conditions including COVID-19
3. Drug therapy
4. Nature of gastrointestinal bleeding (overt, obscure, etc)
5. Length of hospital stay
6. Causes of bleeding
7. Need for transfusion
8. Use of acid inhibitors
9. Need for surgery
10. Other complications of gastrointestinal bleeding
11. Re-bleeding
12. Factors that might help stop bleeding and prevent re-bleeding
13. All-cause mortality including COVID-19

Previous primary outcome measure:

Time trends of the following will be assessed through a review of patient medical records:

1. Demography
2. Coexisting conditions
3. Drug therapy
4. Nature of gastrointestinal bleeding (overt, obscure, etc)
5. Length of hospital stay
6. Causes of bleeding
7. Need for transfusion
8. Use of acid inhibitors
9. Need for surgery
10. Other complications of gastrointestinal bleeding
11. Re-bleeding
12. Factors that might help stop bleeding and prevent re-bleeding
12. All-cause mortality

Key secondary outcome(s))

Subgroup analysis of factors included in the primary outcomes:

1. Role of demographic factors, particularly smoking and alcohol: presence vs. absence.
2. Role of drugs (users vs. non-users), particularly:
 - 2.1. NSAIDs
 - 2.2. Aspirin
 - 2.3. Other anti-platelet agents
 - 2.4. Anticoagulants
 - 2.5. Acid inhibitors
3. Re-admissions following initial bleeding and relevant causative factors
4. Endoscopic findings in upper and lower gastrointestinal tract in cases of overt bleeding
5. Endoscopic findings in obscure bleeding
6. Colonic polyps and cancers in obscure bleeding, bowel screening, and the use of aspirin and NSAIDs

Completion date

31/12/2026

Eligibility

Key inclusion criteria

1. Aged 18 years or older
2. Gastrointestinal bleeding

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

100 years

Sex

All

Key exclusion criteria

1. History of previous gastrointestinal surgery
2. Current pregnancy
3. Current use of cytotoxic drugs

Date of first enrolment

15/09/2018

Date of final enrolment

15/09/2026

Locations

Countries of recruitment

United Kingdom

Scotland

Study participating centre

Department of Gastroenterology
University Hospital Crosshouse
Kilmarnock

United Kingdom
KA2 0BE

Sponsor information

Organisation

Gastroenterology Endowment Fund

ROR

<https://ror.org/041f0qb31>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Gastroenterology Endowment Fund

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary

Other

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
Poster results	abstract/poster	01/05/2020	22/01/2021	No	No