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Causes and outcomes of internal bleeding in the digestive system

Submission date
31/08/2018

Recruitment status
Recruiting

Registration date
06/11/2018

Overall study status
Ongoing

Last Edited
07/07/2025

Condition category
Digestive System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 - whetjher 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

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Epidemiological study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
No participant information sheet available

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 measure
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

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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

Secondary outcome measures
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

Overall study start date
01/01/2002

Completion date
31/12/2026

Eligibility

Key inclusion criteria
1. Aged 18 years or older
2. Gastrointestinal bleeding

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
100 Years

Sex
Both

Target number of participants
All patients presenting with gastrointestinal bleeding, 1996-2026, average 300 patients per annum.

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
Scotland

United Kingdom

Study participating centre
Department of Gastroenterology
University Hospital Crosshouse
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Sponsor information

Organisation
Gastroenterology Endowment Fund

Sponsor details
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/041f0qb31

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Gastroenterology Endowment Fund

Results and Publications

Publication and dissemination plan
Regular analyses will take place, possibly at yearly or shorter intervals. The outcomes will be presented locally and at meetings of learned societies. Publishing in peer-reviewed journals will be considered and aimed for, as appropriate. Our first publication might be ready in the Summer of 2019.

Intention to publish date
30/06/2027

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