International comparison of methods to risk assess patients presenting with upper gastrointestinal bleeding

Submission date	Recruitment status	Prospectively registered		
29/09/2015	No longer recruiting	☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
29/09/2015	Completed	[X] Results		
Last Edited 10/10/2023	Condition category Digestive System	[] Individual participant data		

Plain English summary of protocol

Background and study aims

Upper gastrointestinal bleeding refers to bleeding in the esophagus (foodpipe), stomach or duodenum (first section of the small intestine). Recent guidelines have recommended the use of early risk assessment in patients with upper gastrointestinal bleeding. A number of risk scores have been developed for use in this situation, some of which can be calculated soon after admission to hospital and some of which require endoscopy for calculation. Endoscopy involves a flexible tube with an attached light and camera being passed through the mouth and throat, allowing the doctor to view the esophagus, stomach and duodenum. There have been several studies comparing various combinations of risk scores for upper gastrointestinal bleeding, but we do not know which is the best score for use in clinical practice. The aim of this study is to compare the usefulness of five risk scores in patients with upper gastrointestinal bleeding.

Who can participate?

Patients with upper gastrointestinal bleeding.

What does the study involve?

We collect data including patients' characteristics, blood test results, findings at endoscopy (if undertaken), and any treatments such as blood transfusion, endoscopic treatment and surgery. Bleeding, length of hospital stay and number of deaths are also recorded. The data is then used to compare the predictive abilities of the different risk scores.

What are the possible benefits and risks of participating?

The results of this study will be used to develop a new improved score to improve the prediction of outcome for patients with upper gastrointestinal bleeding. All patient management will be as per standard of care for patients with upper gastrointestinal bleeding. All collected data will be anonymized.

Where is the study run from?

- 1. Glasgow Royal Infirmary, Scotland, UK
- 2. Yale University Hospital, USA

- 3. Odense University Hospital, Denmark
- 4. Royal Cornwall Hospital, Truro, UK
- 5. Singapore General Hospital
- 6. Dunedin Public Hospital, New Zealand
- 7. Humanitas Research Hospital, Milan, Italy
- 8. University Hospital, London, Ontario, Canada

When is the study starting and how long is it expected to run for? November 2013 to April 2015

Who is funding the study? NHS Greater Glasgow & Clyde Endowment Fund (UK).

Who is the main contact?
Dr Adrian Stanley
adrian.stanley@ggc.scot.nhs.uk

Contact information

Type(s)

Scientific

Contact name

Dr Adrian Stanley

Contact details

GI Unit, Walton Building Glasgow Royal Infirmary Castle Street Glasgow United Kingdom G4 OSF +44 (0)141 211 4073 adrian.stanley@ggc.scot.nhs.uk

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

145837

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

IRAS 145837

Study information

Scientific Title

International multicentre prospective study to compare risk scoring system for patients presenting with upper gastrointestinal bleeding

Study objectives

To compare the ability of five existing risk scoring systems (the Full and Clinical Rockall scores, the Italian PNED score, the Glasgow Blatchford (GBS) and the American AIM65 score) to predict outcomes in upper gastrointestinal bleeding (UGIB):

- 1. Need for hospital-based intervention or mortality
- 2. Rebleeding within 7 days
- 3. Length of hospital stay
- 4. 30-day mortality.

Ethics approval required

Old ethics approval format

Ethics approval(s)

West of Scotland Research Ethics Service, 15/01/2014, REC ref: 14/WS/0012, IRAS project ID: 145837

Study design

International observational study

Primary study design

Observational

Study type(s)

Diagnostic

Health condition(s) or problem(s) studied

Upper gastrointestinal bleeding (UGIB)

Interventions

This is an international observational study across seven international sites, to compare five established risk assessment scores in the prediction of clinical outcomes for patients presenting with UGIB. We will collect data to calculate these scores for each patient, then compare the scores' ability to predict the pre-determined end-points.

There are no interventions. We will simply collate data on presentation to hospital with UGIB to allow measurement of the recognised risk scoring systems for this condition. We will then follow up the patients to determine outcomes as described above in the study hypothesis section.

Intervention Type

Other

Primary outcome(s)

Need for hospital-based intervention or 30-day mortality on follow-up

Key secondary outcome(s))

- 1. Rebleeding within 7 days
- 2. Length of hospital stay

Completion date

30/04/2015

Eligibility

Key inclusion criteria

- 1. Patients presenting with haematemesis, coffee-ground vomit, melaena
- 2. Patients presenting with haematochezia and circulatory insufficiency (heart rate >100 bpm and /or systolic blood pressure <100 mmHg)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Αll

Total final enrolment

3012

Kev exclusion criteria

Patients who have an UGIB whilst already an in-patient for other reasons

Date of first enrolment

04/03/2014

Date of final enrolment

30/03/2015

Locations

Countries of recruitment

United Kingdom

England

Canada

Denmark

Italy

New Zealand

Singapore

United States of America

Study participating centre Glasgow Royal Infirmary United Kingdom G4 OSF

Study participating centre Yale University Hospital United States of America CT 06516

Study participating centre Odense University Hospital Denmark DK 5000

Study participating centre Royal Cornwall Hospital United Kingdom TR1 3GZ

Study participating centre Singapore General Hospital Singapore 169608

Study participating centre Dunedin Public Hospital New Zealand 9054

Study participating centre

Humanitas Research Hospital

Italy 20089

Study participating centre University Hospital, London Canada N6A SW9

Sponsor information

Organisation

NHS Greater Glasgow & Clyde (UK)

ROR

https://ror.org/05kdz4d87

Funder(s)

Funder type

Government

Funder Name

NHS Greater Glasgow & Clyde Endowment Fund (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	04/01/2017		Yes	No
Results article	results	01/02/2019	01/04/2020	Yes	No
HRA research summary			28/06/2023	No	No