ISRCTN16235737 https://doi.org/10.1186/ISRCTN16235737

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

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

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
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
145837

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet

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

Secondary outcome measures
1. Rebleeding within 7 days
2. Length of hospital stay

Overall study start date
01/11/2013

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

Age group
Adult

Sex
Both

Target number of participants
3000

Total final enrolment
3012

Key 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

Canada

Denmark

England

Italy

New Zealand

Singapore

United Kingdom

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)

Sponsor details
R&D Management Office
Western Infirmary
Tennant Institute
38 Church Street
Glasgow
Scotland
United Kingdom
G11 6NT

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05kdz4d87

Funder(s)

Funder type
Government

Funder Name
NHS Greater Glasgow & Clyde Endowment Fund (UK)

Results and Publications

Publication and dissemination plan
The results of the study will be presented at international conferences in gastroenterology and will be published in an international peer-reviewed journal.

Intention to publish date

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