

UK GRACE Risk Score Intervention Study

Submission date 09/01/2017	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 12/01/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 27/06/2025	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Acute coronary syndrome (ACS) refers to a group of conditions due to decreased blood flow in the coronary arteries such that part of the heart muscle is unable to function properly or dies. It encompasses a range of sudden heart conditions, including heart attack and unstable angina attack (sudden chest pain). ACS mainly happens due to narrowing of the blood vessels which supply the heart due to a build-up of plaque (a fatty, sticky substance) on the walls of arteries. The GRACE risk score tool is a special tool which can be used by healthcare professionals (such as doctors) to calculate the risks of further heart attack or death after acute coronary syndrome (type of unstable angina attack or heart attack), by looking at medical information that is routinely collected during hospital stays. The aim of this study is to find out whether there is a difference in patient's health status following an unstable angina attack or a heart attack if treated according to usual care or if treated using the GRACE risk score tool.

Who can participate?

Adults who have been admitted to hospital with a suspected acute coronary syndrome.

What does the study involve?

Participating hospitals are randomly allocated to one of two groups. Hospitals in the first group use the GRACE risk score tool within routine clinical assessment and management procedures. This involves individual participants who agree to take part having their GRACE risk score calculated and used to help decide their treatment. Hospitals in the second group continue to follow their current practice. In both groups, participants complete a general health assessment and a short questionnaire at the start of the study and then again 12 months later to assess their health status. Participants' long-term progress relating to their heart condition is also assessed by reviewing electronic medical records.

What are the possible benefits and risks of participating?

There are no guaranteed benefits of participating, however the information gained from this study could help improve the treatment of people with ACS in the future. There are no notable risks involved with participating.

Where is the study run from?

Thirteen NHS hospitals in England (UK)

When is the study starting and how long is it expected to run for?
May 2015 to December 2021

Who is funding the study?
British Heart Foundation (UK)

Who is the main contact?
Ms Rachael Gilberts, R.M.Gilberts@leeds.ac.uk

Contact information

Type(s)
Public

Contact name
Ms Rachael Gilberts

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 32356

Study information

Scientific Title
Effectiveness of the GRACE risk score on the management and outcome of patients hospitalised with non-ST elevation acute coronary syndrome

Acronym
UKGRIS

Study objectives

Study aim:

The aim of this study is to evaluate the effectiveness of the systematic clinical application of the GRACE risk score.

Hypothesis:

Compared with current standard care, the implementation of the GRACE risk score tool by healthcare professionals for patients hospitalised with NSTEMI increases the use of Class 1 guideline-indicated therapies for the management of NSTEMI and reduces the composite endpoints of cardiovascular death, non-fatal myocardial infarction, new onset heart failure (with admission) and cardiovascular readmission at 12 months.

Ethics approval required

Old ethics approval format

Ethics approval(s)

NRES Committee North East – Newcastle & North Tyneside 1, 06/11/2014, ref: 14/NE/1180

Study design

Randomized; Interventional; Design type: Process of Care, Management of Care

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Acute coronary syndrome (ACS)

Interventions

Sites are randomised centrally using minimisation including a random element at the CTRU to either the intervention (use of the GRACE risk score) or to current standard care at their site on a 1:1 basis stratified by hospital ACS Volume and primary PCI capability. Sites are randomised prior to opening to recruitment. Sites are excluded from participating in the study if they currently use the GRACE risk score for guiding treatment in this group of participants. Participants are then registered onto the study following a site opening to recruitment and the participant consenting to take part in the study.

Intervention arm: The trial will aim to embed the GRACE risk score tool within routine clinical assessment and management procedures at each of the hospitals randomised to the intervention. Each consenting participant will have their GRACE risk score and corresponding risk

of six month mortality estimated by the appointed local research staff / healthcare professional as soon as possible after admission (ideally within twelve hours). Each participant will be classified as either 'low' (score:<109), 'intermediate' (score: 109 to 140) or 'high' (score: >140) risk estimate of six month mortality and this will be clearly recorded on the Risk Scores CRF with a list of abbreviated guideline recommendations for the management of NSTEMI. The trial will collect recommendations followed and reasons for not following recommendations.

Control arm: Participants will be registered into the study and the site will continue with their current practice. CTRU staff will be in regular contacts with sites during the recruitment phase to ensure sites do not change their practices to incorporate the GRACE risk score in their treatment of this group of participants.

All participants will consent to participate in this study following their admission to hospital. Following consent their baseline information will be collected and, dependent on the arm of the trial, their GRACE risk score will be calculated and their treatment recommendations recorded or normal practice will be followed. The recommended timelines for this happening is within 12 hours of the participant being admitted to hospital. Following on from this, a member of the research team will work through a frailty score with the participant and then the participant will complete a short questionnaire.

On discharge from hospital (or death) further data will be collected as to what treatment and medication the participant received during their admission. 12 months after the patient was registered into the study, the patient will be posted a further short questionnaire to complete and send back to the CTRU. The study team will also be applying for follow up data for the participants via electronic health records.

Intervention Type

Other

Phase

Phase III

Primary outcome measure

Current primary outcome measure as of 04/06/2021:

1. The proportion of care processes (Class 1 guideline-indicated therapies) received across all participants in each hospital as assessed using care processes reported from time of onset of chest pain until discharge from hospital (or death) as recorded on the end of hospital stay CRF.
2. Composite endpoint of cardiovascular death, non-fatal myocardial infarction, new onset heart failure (with hospitalisation) and cardiovascular readmissions at 12 months assessed through electronic health record review at 12 and 24 months

Previous primary outcome measure:

1. The proportion of care processes (Class 1 guideline-indicated therapies) received across all participants in each hospital as assessed using care processes reported from time of onset of chest pain until discharge from hospital (or death) as recorded on the end of hospital stay CRF.
2. Composite endpoint of cardiovascular death, non-fatal myocardial infarction, new onset heart failure (with hospitalisation) and cardiovascular readmissions at 12 months assessed through electronic health record review at 12 months

Secondary outcome measures

Current secondary outcome measures as of 04/06/2021:

1. Health-related quality of life is measured using the EQ-5D-5L questionnaire at baseline and 12 months
2. Unscheduled revascularisations within 12 months of initial presentation are assessed through electronic health record review at 12 months
3. Length of hospital stay within 12 and 24 months of initial presentation is assessed through electronic health record review at 12 and 24 months
4. Individual components of the composite endpoints of cardiovascular death, non-fatal myocardial infarction, new onset heart failure (with hospitalisation) and cardiovascular readmission at 12 and 24 months assessed through electronic health record review at 12 and 24 months

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Overall study start date

11/05/2015

Completion date

31/12/2021

Eligibility

Key inclusion criteria

Research sites inclusion criteria:

1. Acute hospital participating in MINAP
2. Willing to implement the GRACE risk score tool

Patient inclusion criteria:

1. Age greater than or equal to 18 years (no upper age limit)
2. Symptoms consistent with acute cardiac ischaemia for >10 min within 24 hours of presentation to hospital
3. One of the following and/or at least two of the High Risk Features:
 - 3.1. ECG changes:
 - 3.1.1. Transient ST-segment elevation of 0.5 mm in 2 or more contiguous leads;
 - 3.1.2. ST-segment depression of 0.5 mm in 2 or more contiguous leads;
 - 3.1.3. New T wave inversion of 1 mm in 2 or more contiguous leads;
 - 3.1.4. New Q waves [1/3 height of R wave or >0.04 seconds];
 - 3.1.5. New R wave > S wave in lead V1; or,
 - 3.1.6. New left bundle branch block
 - 3.2. Elevated cardiac biomarkers:
 - 3.2.1. Troponin T or I above the upper reference limit (URL);
 - 3.2.2. CK-MB 2x URL; or,

- 3.2.3. If there is no CK-MB available, then total CK greater than the local URL
- 3.3. Documented coronary artery disease:
 - 3.3.1. History of MI or angina;
 - 3.3.2. Congestive cardiac failure due to ischaemia;
 - 3.3.3. Resuscitated sudden cardiac death;
 - 3.3.4. Prior or new positive stress test with or without imaging;
 - 3.3.5. Prior or new, cardiac catheterisation, percutaneous coronary artery intervention or coronary artery bypass graft surgery documenting coronary artery disease
- 3.4. At least 2 of the following High Risk features:
 - 3.4.1. Haemodynamic compromise (SBP <90 mmHg and HR >100 bpm)
 - 3.4.2. Left ventricular systolic dysfunction (LVEF <0.40);
 - 3.4.3. Presence of known diabetes mellitus
 - 3.4.4. Documentation of chronic kidney disease (estimated GFR <60 ml/min/m²)
- 4. Willing and able to provide written informed consent

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Planned Sample Size: 9000; UK Sample Size: 3000

Total final enrolment

3050

Key exclusion criteria

Research sites exclusion criteria:

GRACE risk tool already implemented.

Patient exclusion criteria:

1. Patients presenting at hospital due to an acute ST-segment elevation myocardial infarction (STEMI)
2. Patients presenting at hospital with an ACS accompanied with, or precipitate by significant co-morbidity e.g. motor vehicle accident, trauma, severe gastrointestinal bleeding
3. Peri-operative or peri-procedural MI
4. Patients already recruited into the study

Date of first enrolment

23/01/2017

Date of final enrolment

31/12/2019

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Yeovil District Hospital

Higher Kingston

Yeovil

United Kingdom

BA21 4AT

Study participating centre

Royal Lancaster Infirmary

Ashton Road

Lancaster

United Kingdom

LA1 4RP

Study participating centre

Furness General Hospital

Dalton Lane

Barrow-in-Furness

United Kingdom

LA14 4LF

Study participating centre

Royal Chesterfield Hospital

Top Road

Calow

Chesterfield

United Kingdom

S44 5BL

Study participating centre

Leighton Hospital

Middlewich Road

Crewe
United Kingdom
CW1 4QJ

Study participating centre
York Hospital
Wigginton Road
York
United Kingdom
YO31 8HE

Study participating centre
Royal Blackburn Hospital
Haslingden Road
Blackburn
United Kingdom
BB2 3HH

Study participating centre
Conquest Hospital
The Ridge
St Leonards On Sea
United Kingdom
TN37 7RD

Study participating centre
Royal Sussex County Hospital
Sussex Cancer Centre
Eastern Road
Brighton
United Kingdom
BN2 5BE

Study participating centre
Torbay District General Hospital
Heart and Lung Unit
Lowes Bridge
Torquay
United Kingdom
TQ2 7AA

Study participating centre**West Middlesex University Hospital**

Chelsea & Westminster Hospital NHS Foundation Trust
Twickenham Road
Isleworth
United Kingdom
TW7 6AF

Study participating centre**Blackpool Victoria Hospital**

Whinney Heys Road
Blackpool
United Kingdom
FY3 8NR

Study participating centre**East Surrey Hospital**

Canada Avenue
Redhill
United Kingdom
RH1 5RH

Sponsor information

Organisation

University of Leeds

Sponsor details

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Room 10.110, Level 10
Worsley Building
Clarendon way
Leeds
England
United Kingdom
LS2 9NL
+44 113 3437587
governance-ethics@leeds.ac.uk

Sponsor type

University/education

ROR

<https://ror.org/024mrx33>

Funder(s)

Funder type

Charity

Funder Name

British Heart Foundation

Alternative Name(s)

the_bhf, The British Heart Foundation, BHF

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer reviewed journal.

Intention to publish date

31/03/2023

Individual participant data (IPD) sharing plan

De-identified individual participant data datasets generated and/or analysed during the current study will be available upon request from the Clinical Trials Research Unit, University of Leeds (contact CTRU-DataAccess@leeds.ac.uk in the first instance). Data will be made available at the end of the trial, i.e. usually when all primary and secondary endpoints have been met and all key analyses are complete. Data will remain available from then on for as long as CTRU retains the data.

CTRU makes data available by a 'controlled access' approach. Data will only be released for legitimate secondary research purposes, where the Chief Investigator, Sponsor and CTRU agree that the proposed use has scientific value and will be carried out to a high standard (in terms of scientific rigour and information governance and security) and that there are resources available to satisfy the request. Data will only be released in line with participants' consent, all applicable laws relating to data protection and confidentiality, and any contractual obligations to which the

CTRU is subject. No individual participant data will be released before an appropriate agreement is in place setting out the conditions of release. The agreement will govern data retention, usually stipulating that data recipients must delete their copy of the released data at the end of the planned project.

The CTRU encourages a collaborative approach to data sharing and believes it is best practice for researchers who generated datasets to be involved in subsequent uses of those datasets. Recipients of trial data for secondary research will also receive data dictionaries, copies of key trial documents and any other information required to understand and reuse the released datasets.

The conditions of release for aggregate data may differ from those applying to individual participant data. Requests for aggregate data should also be sent to the above email address to discuss and agree suitable requirements for release.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		05/09/2019	12/08/2022	Yes	No
Results article		14/06/2023	15/06/2023	Yes	No
HRA research summary			28/06/2023	No	No
Other publications	Post hoc analysis	26/06/2025	27/06/2025	Yes	No