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UK GRACE Risk Score Intervention Study

Submission date
09/01/2017

Recruitment status
No longer recruiting

Registration date
12/01/2017

Overall study status
Completed

Last Edited
27/06/2025

Condition category
Circulatory System

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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. Hosptials 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

Central Portfolio Management System (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 NSTEACS increases the use of Class 1

guideline-indicated therapies for the management of NSTEACS 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

Primary study design
Interventional

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

Study type(s)
Treatment

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 NSTEACS. 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(s)
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

Key secondary outcome(s)
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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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 months assessed through electronic health record review at 12 months

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

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
United Kingdom

England

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
Wiggington 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

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
Charity

Funder Name
British Heart Foundation

Alternative Name(s)
The British Heart Foundation, the_bhf, BHF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

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?
Results article		14/06/2023	15/06/2023	Yes	No
Protocol article		05/09/2019	12/08/2022	Yes	No
HRA research summary			28/06/2023	No	No
Other publications	Post hoc analysis	26/06/2025	27/06/2025	Yes	No