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A study to evaluate the benefit of medical therapy versus angiography and stenting in patients with heart attacks - The BHF SENIOR RITA Trial

Submission date
03/10/2016

Recruitment status
No longer recruiting

Registration date
19/10/2016

Overall study status
Completed

Last Edited
04/10/2024

Condition category
Circulatory System

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Coronary artery disease (CAD), also known as ischemic heart disease, is one of the leading causes of death worldwide. CAD develops because of the build-up of fatty deposits (plaque) on the walls of the coronary arteries (the arteries that supply the heart with oxygen-rich blood), leading to a range of problems, including heart attack and angina (chest pain). Over recent years, there have been improvements in medications and technologies to treat CAD but these have been primarily tested in younger patients. Previous studies suggest that older patients (75 years and over) are not well represented in clinical research and these patients, in particular those who are frail and those suffering from other conditions, are less likely to receive advanced medications and medical procedures. This study will look at patients over the age of 75 who have come to the hospital after having a heart attack. The aim of this study is to find out whether undergoing a procedure called an angiography (which shows whether there are any blockages in the heart arteries) as well as the latest medications recommended for heart attacks is a more effective treatment strategy than medication alone in terms of prolonging life.

Who can participate?
Adults over the age of 75 who have been admitted to a participating hospital with a heart attack.

What does the study involve?
Participants are randomly allocated to one of two groups. In the first group, patients will receive the latest medications recommended for heart attacks. In the second group, in addition to these medications, patients will have coronary angiography. This involves having a substance called contrast medium is injected into the body which highlights the blood vessels in the heart as it moves through them. An X-ray machine is then used to view the arteries to see if there are any blockages. If there is a blockage, then participants may undergo surgery to reopen the blocked blood vessels if appropriate. The techniques used in this study are standard techniques and are performed by experienced cardiologists (heart doctors). At the start of the study and then after 6 months and 1 year, participants complete a range of questionnaires to assess their frailty,

quality of life and cognitive function (thinking and memory skills). Information about frailty and quality of life is also collected annually for a 5-year period in order to see which of the two groups live better and longer.

What are the possible benefits and risks of participating?
There are no direct benefits to patients other than receiving close follow-ups via clinic visits and telephone interviews that are not routinely offered in the NHS. Participation and the results of the study will help inform the medical community on how best to treat future patients with this condition. There are no notable risks involved with participating in this study.

Where is the study run from?
Freeman Hospital and 24 other NHS hospitals in England, Scotland and Wales (UK)

When is the study starting and how long is it expected to run for?
January 2015 to March 2024

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

Who is the main contact?
Prof. Vijay Kunadian, vijay.kunadian@newcastle.ac.uk

Contact information

Type(s)
Scientific

Contact name
Prof Vijay Kunadian

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Additional identifiers

EudraCT/CTIS number

IRAS number
Nil known

ClinicalTrials.gov number
NCT03052036

Secondary identifying numbers
CPMS 31701

Study information

Scientific Title
The British Heart Foundation older patients with non-ST SEgmeNt elevatIOn myocaRdial infarction Randomized Interventional TreAtment Trial

Acronym
BHF SENIOR-RITA

Study objectives
Primary objective:
To determine the impact of a routine invasive strategy on one-year cardiovascular death and non-fatal myocardial infarction (MI) compared with a conservative treatment strategy in older patients (≥75 years) with NSTEMI.

Secondary objectives:
To determine the impact of a routine invasive strategy compared with a conservative strategy on:
1. All-cause death
2. Cardiovascular or non-cardiovascular death
3. Recurrent myocardial infarction
4. Urgent coronary revascularisation
5. Recurrent hospitalisation for myocardial infarction
6. Hospitalization for heart failure
7. Stroke
8. Bleeding (BARC 2)
9. Procedural and in-hospital complications
10. Length of time spent at home
11. Frailty and quality of life

Ethics approval required
Old ethics approval format

Ethics approval(s)
North East - Newcastle & North Tyneside 2 Research Ethics Committee, 03/08/2016, ref: 16/NE/0238

Study design
Randomized; Both; Design type: Treatment, Surgery

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
Non-ST segment elevation myocardial infarction

Interventions
Following consent, patients will be randomized to one of two groups.

Group 1: Participants undergo a coronary angiography (heart artery X-ray test) and, if appropriate, coronary revascularisation (treatment with balloon or stents or bypass surgery) plus optimal medical therapy.
Group 2: Participants receive conservative management (optimal medical therapy alone)

The study interventions are standard of care in patients with coronary artery disease and will be performed by interventional cardiologists at local sites with considerable experience in these clinical procedures.

Following randomization, all baseline data required for the study including baseline demographics, medical history/co-morbidities (Charlson Index), risk factors, current NSTEMI /admission details, medications history will be collected during hospitalisation. Results of investigations performed as part of routine care of patients including full blood count, serum urea, creatinine concentrations, lipids, glucose and peak troponin concentration will be recorded. Data from baseline ECG will be collected for information on ST-T changes. Additional study related data including MoCA scores (baseline and 1-year), frailty scores, quality of life (EQ-5D-5L), use of health services and patient costs will also be collected. Echocardiographic data will be collected where available. Angiographic and procedural data will be collected from those that undergo invasive care. Detailed angiographic analysis will be carried out in Newcastle.

Rockwood and Fried frailty score will be calculated for all patients at baseline, 6 months, 1 year and yearly thereafter for 5 years.

Quality of life (QOL) assessments using the EQ-5D-5L will be requested at baseline (pre-randomisation), 30 days, 3 months, 6 months, and at 1 year. Data will be collected during research clinic follow-up visits where feasible (i.e. at baseline, 6 and 12 months). Where this is not feasible, patients will be given the questionnaires to take home at the appropriate trial visits or will be posted out to patients. Patients will be asked to complete the questionnaires and return the completed questionnaires. If questionnaires are not returned after 2 weeks, data will be collected by telephone interviews with the patient or with their carer, where possible. In addition, for the EQ-5D-5L, a proxy-rated version is available for relatives/carers to rate how they expect the patient views their current quality of life. Proxy data (EQ-5D-5L proxy version 2) will be collected at all time points. The relatives/carers will be asked to complete a simple contact form to provide their personal details and to sign this form to agree to Newcastle Clinical Trials Unit having their identifiable information. This will be returned to the trial management team who will send the questionnaires.

In addition, costs of treatment in both trial arms will be quantified by collecting data on the use of secondary, primary and personal social services (PSS) at baseline (and at each follow-up period) in a bespoke health and PSS utilisation questionnaire.

Patients will be invited to attend research clinics for follow-up visits where feasible. Where this is not feasible, telephone follow-up will be carried out. If required, home visits by the research team will be organised in order to obtain follow-up data from patients.

Intervention Type
Mixed

Primary outcome measure
Time to cardiovascular death or non-fatal MI within one year is determined by analysing the number of deaths one year after randomisation.

Secondary outcome measures
1. All-cause, cardiovascular and non-cardiovascular death rates are measured using hospital records and ONS continuously until study end
2. Recurrent myocardial infarction rates are measured using patient records and HES data during index hospitalisation (Baseline), 6 months, 1 year and annually up to 10 years
3. Hospitalisation for heart failure rate is measured using patient records during index hospitalisation (Baseline), 6 months, 1 year and annually up to 10 years
4. Urgent coronary revascularisation rate is measured using patient records during index hospitalisation (Baseline), 6 months, 1 year and annually up to 10 years
5. Recurrent hospitalisation for myocardial infarction is measured using patient records during index hospitalisation (Baseline), 6 months, 1 year and annually up to 10 years
6. Stroke rate is measured using patient records and HES data during index hospitalisation (Baseline), 6 months, 1 year and annually up to 10 years
7. Bleeding (BARC ≥2) rate is measured using patient records and HES data during index hospitalisation (Baseline), 6 months, 1 year and annually up to 10 years
8. Procedural complication (including death, MI, major bleeding (BARC definition), ≥ 25% increase in serum creatinine concentration from baseline, need for renal replacement therapy, stroke) rate is measured using hospital records during index hospitalisation (baseline)
9. Length of time spent at home is measured using the Time & Travel Questionnaire- telephone or clinic visit at 6 months
10. Frailty is measured using Fried and Rockwood frailty scores at baseline 6 months and 1 year and annually up to 5 years
11. Quality of Life is measured using EQ-5D-5L and quality adjusted life years (QALY) at baseline, 6 months and 1 year and annually up to 5 years
12. Costs to the NHS and personal social services are measured using a questionnaire at clinic or telephone at baseline, 6 months and 1 year and annually up to 5 years
13. Incremental cost per QALY gained at 1 year is measured using a questionnaire at clinic or telephone at 1 year

Overall study start date
10/01/2014

Completion date
31/03/2024

Eligibility

Key inclusion criteria
1. Aged ≥75 years
2. Type 1 NSTEMI during index hospitalisation

Participant type(s)
Patient

Age group
Senior

Lower age limit
75 Years

Sex
Both

Target number of participants
Planned Sample Size: 1680; UK Sample Size: 1680

Total final enrolment
1516

Key exclusion criteria
1. Patients presenting with STEMI or unstable angina
2. Patients with cardiogenic shock
3. Patients with known life expectancy
4. Patients in whom neither the patient nor the consultee are able and willing to provide written informed consent
5. Previous inclusion in the BHF SENIOR-RITA trial
6. Inability to undergo invasive coronary angiography, such as no vascular access site, or absolute contraindication to coronary revascularisation

Date of first enrolment
24/10/2016

Date of final enrolment
31/03/2023

Locations

Countries of recruitment
England

Scotland

United Kingdom

Wales

Study participating centre
Freeman Hospital
Freeman Road
Newcastle upon Tyne
United Kingdom
NE7 7DN

Study participating centre
Royal Victoria Infirmary
Queen Victoria Road
Newcastle upon Tyne
United Kingdom
NE1 4LP

Study participating centre
Aberdeen Royal Infirmary
Cardiology
Polwarth Building
Foresterhill
Aberdeen
United Kingdom
AB25 2ZD

Study participating centre
Victoria Hospital
Blackpool Teaching Hospitals NHS Foundation Trust
Whineys Heys Road
Blackpool
United Kingdom
FY8 8NR

Study participating centre
Borders General Hospital
Huntlyburn
Melrose
United Kingdom
TD6 9BS

Study participating centre

University Hospital Wales
Heath Park
Cardiff
United Kingdom
CF14 4XW

Study participating centre
Chesterfield Royal Hospital
Chesterfield Road
Calow
Chesterfield
United Kingdom
S44 5BL

Study participating centre
Tayside Medical Science Centre
Ninewells Hospital
Level 3
George Pirie Way
Dundee
United Kingdom
DD1 9SY

Study participating centre
Darlington Memorial Hospital
Hollyhurst Road
Darlington
United Kingdom
DL3 6HX

Study participating centre
Conquest Hosptial
East Sussex Healthcare NHS Trust
St. Anne’s House
729 The Ridge
St. Leonards-on-sea
United Kingdom
TN37 7PT

Study participating centre

Royal Infirmary of Edinburgh
51 Little France Crescent
Edinburgh
United Kingdom
EH16 4SA

Study participating centre
Hairmyres Hospital
Eaglesham Road
East Kilbride
United Kingdom
G75 8RG

Study participating centre
Lincolnshire Heart Centre
United Lincolnshire Healthcare Trust
Lincoln County Hospital
Greetwell Road
Lincoln
United Kingdom
LN2 5QY

Study participating centre
The James Cook University Hospital
Marton Road
Middlesbrough
United Kingdom
TS4 3BW

Study participating centre
University Hospital of North Tees
Hardwick Road
Stockton-on-Tees
United Kingdom
TS19 8PE

Study participating centre
Pinderfields Hospital
Aberford Road

Wakefield
United Kingdom
WF1 4DG

Study participating centre
Northern General Hospital
Cardiovascular Research Unit
Centre for Biomedical Research
Barnsley Road
Sheffield
United Kingdom
S5 7AU

Study participating centre
Wythenshawe Hospital
Southmoor Road
Manchester
United Kingdom
M23 9LT

Study participating centre
South Tyneside District Hospital
Harton Lane
South Shields
United Kingdom
NE34 0DY

Study participating centre
Morriston Hospital
Abertawe Bro Morgannwg University Health Board
Swansea
United Kingdom
SA6 6NL

Study participating centre
Wansbeck General Hospital
Northumbria Healthcare NHS Foundation Trust
Woodhorn
Ashington
United Kingdom
NE63 9JJ

Study participating centre
Royal Alexandra Hospital
Corsebar Road
Paisley
United Kingdom
PA2 9PN

Study participating centre
Basildon University Hospital
Nethermayne
Basildon
United Kingdom
SS16 5NL

Study participating centre
University Hospital Ayr
Dalmellington Road
Ayr
United Kingdom
KA6 6DX

Study participating centre
Queen Elizabeth Hospital
Queen Elizabeth Avenue
Gateshead
United Kingdom
NE9 6SX

Sponsor information

Organisation
The Newcastle Upon Tyne Hospitals NHS Foundation Trust

Sponsor details
Freeman Hospital
Freeman Road
High Heaton
Newcastle-Upon-Tyne
England

United Kingdom
NE7 7DN

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05p40t847

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
The study will be presented at a major cardiovascular scientific session and published in a high impact peer-reviewed journal.

Intention to publish date
30/09/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Vijay Kunadian (Chief Investigator), Vijay.kunadian@newcastle.ac.uk.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			26/07/2023	No	No
Results article		01/09/2024	04/09/2024	Yes	No