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Revascularisation or medical therapy in elderly patients with acute anginal syndromes

Submission date 13/03/2014	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 13/03/2014	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 13/10/2021	**Condition category** Circulatory System	[_] Individual participant data

Plain English summary of protocol

Background and study aims
Acute coronary syndrome (ACS) is a term referring to various heart conditions, including heart attacks. Despite the enormous amount of research around ACS, there is only a very small amount of data on the management of ACS in the elderly, octogenarian population. About 33% of all ACS episodes in the UK occur in patients aged over 75. The incidence of ACS in the octogenarian is projected to increase due to advances in ACS treatment in an aging population. A non-ST segment elevation myocardial infarction (NSTEMI) is a less serious heart attack where the supply of blood to the heart is only partially blocked. Treatment for NSTEMI can be divided into two groups: optimal medical therapy (OMT) or OMT plus revascularisation. OMT consists of the medications heparin, aspirin, clopidogrel, beta blocker and a statin followed by a plan to optimise long-term medical treatment in order to reduce future cardiac events. OMT plus revascularisation refers to OMT together with a coronary angiogram (X-ray of the heart) followed by either stent insertion or coronary artery bypass graft surgery (CABG). As yet, no large studies comparing OMT with OMT plus revascularisation have been undertaken in octogenarian patients. The small amount of data that is available appears to demonstrate a greater benefit from revascularisation, yet it is common for this to be denied to them. Our aim is to recruit over 700 patients aged 80 or over to a study comparing OMT with OMT plus revascularisation.

Who can participate?
NSTEMI patients aged 80 or over

What does the study involve?
Participants are randomly allocated to be treated with either OMT or OMT plus revascularisation.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Brighton and Sussex University Hospitals NHS Trust (UK)

When is the study starting and how long is it expected to run for?
April 2014 to September 2019

Who is funding the study?
Medtronic International Trading Sàrl

Who is the main contact?
Mr Duncan Fatz
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT02086019

Secondary identifying numbers
16226

Study information

Scientific Title
Revascularisation or medical therapy in elderly patients with acute anginal syndromes

Acronym
RINCAL

Study objectives

The aim is to recruit over 700 patients 80 years or over to a randomised controlled trial comparing revascularisation plus OMT (invasive arm) versus optimal medical therapy (conservative arm).

Ethics approval required
Old ethics approval format

Ethics approval(s)
London - Brighton & Sussex Research Ethics Committee, 27/11/2013, ref: 13/LO/1082

Study design
Randomised; Interventional; Design type: Not specified

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
Topic: Cardiovascular; Subtopic: Cardiovascular (all Subtopics); Disease: Atherothrombosis

Interventions
Percutaneous coronary intervention (PCI) or Coronary Artery Bypass Graft (CABG)

Intervention Type
Mixed

Primary outcome measure
Composite at 1 year of:
1. Death
2. Non-fatal myocardial infarction

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/04/2014

Completion date

01/09/2019

Eligibility

Key inclusion criteria
1. Age 80 or over
2. Non STEMI characteristic chest pain accompanied by typical ischaemic ECG changes a troponin rise
3. Suitable for conservative or invasive strategy

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
Planned Sample Size: 750; UK Sample Size: 750

Total final enrolment
251

Key exclusion criteria
1. Acute STEMI
2. Cardiogenic shock
3. Lack of suitability for whatever clinical reason to be randomised (any condition in the opinion of the Investigator would make it unsafe or unsuitable for the patient to participate in the study)
4. Platelet count =50 x 109/mm3
5. Patient life expectancy < 1 year
6. Known allergies to clopidogrel, aspirin, heparin, stainless steel, IV contrast or stent
7. Drug elutant
8. Recent major GI haemorrhage (within 3 months)
9. Any previous cerebral bleeding episode
10. Participation in another investigational drug or device study
11. Patient unable to give consent
12. Clinical decision precluding the use of stents

Date of first enrolment
01/04/2014

Date of final enrolment
01/09/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Brighton and Sussex University Hospitals NHS Trust
Brighton
United Kingdom
BN2 1ES

Sponsor information

Organisation
Brighton & Sussex University Hospitals NHS Trust (UK)

Sponsor details
CIRU, Royal Sussex County Hospital
Eastern Road
Brighton
England
United Kingdom
BN2 5BE

Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Industry

Funder Name
Medtronic; Grant Codes: UK- SHQ SBU

Alternative Name(s)
Medtronic Inc.

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location

United States of America

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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 Adam de Belder (a.debelder@nhs.net).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		17/05/2021	11/10/2021	Yes	No
HRA research summary			28/06/2023	No	No