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# Revascularisation or medical therapy in elderly patients with acute anginal syndromes

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| **Submission date**<br>13/03/2014 | **Recruitment status**<br>No longer recruiting | [X] Prospectively registered<br>[_] Protocol |
| **Registration date**<br>13/03/2014 | **Overall study status**<br>Completed | [_] Statistical analysis plan<br>[X] Results |
| **Last Edited**<br>13/10/2021 | **Condition category**<br>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
duncan.fatz@bsuh.nhs.uk

# Contact information

### Type(s)
Scientific

### Contact name
Mr Duncan Fatz

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# Additional identifiers

### ClinicalTrials.gov (NCT)
NCT02086019

### Protocol serial number
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

### Study type(s)
Treatment

### 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(s)
Composite at 1 year of:
1. Death
2. Non-fatal myocardial infarction

### Key secondary outcome(s))
Not provided at time of registration

### 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

### Healthy volunteers allowed
No

### Age group

Senior

### Sex
All

### 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
United Kingdom

England

### 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)

# 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

### 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 |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |