

Intervention versus conservative treatment strategy in patients with unstable angina or non-ST elevation myocardial infarction (the Third Randomised Intervention Treatment of Angina trials [RITA 3])

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|--|---|---|
| Submission date 16/11/2001 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 16/11/2001 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 03/08/2015 | Condition category Circulatory System | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol
Not provided at time of registration

Study website
<http://www.rita3.org.uk>

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

RG/96001

Study information

Scientific Title

Intervention versus conservative treatment strategy in patients with unstable angina or non-ST elevation myocardial infarction (the Third Randomised Intervention Treatment of Angina trials [RITA 3])

Acronym

RITA 3

Study objectives

Current guidelines suggest that, for patients at moderate risk of death from unstable coronary-artery disease, either an interventional strategy (angiography followed by revascularisation) or a conservative strategy (ischaemia-driven or symptom-driven angiography) is appropriate. We aimed to test the hypothesis that an interventional strategy is better than a conservative strategy in such patients.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Multi-centre national ethics committee approval and local ethics committee approval were obtained

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Patient information can be found on the website at: <http://www.rita3.org.uk/>

Health condition(s) or problem(s) studied

Unstable angina/non-ST elevation myocardial infarction

Interventions

Angiography followed by Percutaneous Coronary Intervention (PCI) or Coronary Artery Bypass Grafting (CABG) versus conservative management.

Intervention Type

Procedure/Surgery

Primary outcome measure

The co-primary endpoints were a combined rate of death, non-fatal myocardial infarction, or refractory angina at 4 months; and a combined rate of death or non-fatal myocardial infarction at 1 year. Analysis was by intention to treat.

Secondary outcome measures

Secondary outcomes included subsequent revascularisation, angina scores, anti-anginal medication, quality-of-life scores, and health-economic evaluations.

Overall study start date

12/11/1997

Completion date

31/12/2006

Eligibility

Key inclusion criteria

Patients within 24 hours of an index episode of ischaemic pain at rest or patients will have documented evidence of coronary disease with at least one of:

1. Electrocardiogram (ECG) evidence of myocardial ischaemia
2. Pathological Q waves on an ECG suggesting previous myocardial infarction
3. Arteriographically proven coronary disease on a previous angiogram

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

1810

Key exclusion criteria

All those with probable evolving myocardial infarction, including those for whom reperfusion therapy was indicated, were ineligible. Those in A1 whom new pathological Q waves developed, or those with creatine kinase or creatine kinase Myocardial Bands (MB) concentrations twice the upper limit of normal before randomisation, were excluded. Also excluded were those with

myocardial infarction within the previous month, Percutaneous Coronary Intervention (PCI) in the preceding 12 months, or Coronary Artery Bypass Grafting (CABG) at any time.

Date of first enrolment

12/11/1997

Date of final enrolment

31/12/2006

Locations

Countries of recruitment

Scotland

United Kingdom

Study participating centre

The University of Edinburgh

Edinburgh

United Kingdom

EH16 4SB

Sponsor information

Organisation

British Heart Foundation (UK)

Sponsor details

14 Fitzhardinge Street

London

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research@bhf.org.uk

Sponsor type

Charity

Website

<http://www.bhf.org.uk>

ROR

<https://ror.org/02wdwnk04>

Funder(s)

Funder type

Charity

Funder Name

British Heart Foundation (UK) (ref: RG/96001) - plus donation from Aventis to the British Heart Foundation

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|------------------------------------|---|--------------|------------|----------------|-----------------|
| Results article | results of impact of gender | 01/09/2004 | | Yes | No |
| Results article | one-year results | 18/01/2005 | | Yes | No |
| Results article | five-year outcomes results | 01/09/2005 | | Yes | No |
| Results article | patient management and disease events results | 01/10/2006 | | Yes | No |
| Results article | cost effectiveness study results | 01/06/2008 | | Yes | No |
| Other publications | collaborative analysis | 31/01/2012 | | Yes | No |
| Other publications | collaborative analysis | 01/02/2012 | | Yes | No |
| Other publications | collaborative analysis | 01/02/2012 | | Yes | No |
| Results article | 10-year results | 04/08/2015 | | Yes | No |