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])

Submission date	Recruitment status No longer recruiting	Prospectively registered			
16/11/2001		Protocol			
Registration date	Overall study status	Statistical analysis plan			
16/11/2001	Completed	[X] Results			
Last Edited 03/08/2015	Condition category Circulatory System	[] Individual participant data			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

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 coronaryartery 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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s))

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

Scotland

Study participating centre
The University of Edinburgh
Edinburgh
United Kingdom
EH16 4SB

Sponsor information

Organisation

British Heart Foundation (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

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

No
No
No
No
No
Yes
Yes