ISRCTN07752711 https://doi.org/10.1186/ISRCTN07752711

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

Plain English summary of protocol
Not provided at time of registration

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

Contact information

Type(s)
Scientific

Contact name
Prof Keith AA Fox

Contact details
Chancellor's Buiding
49 Little France Crescent
Edinburgh
United Kingdom
EH16 4SB
+44 (0)131 536 2743
k.a.a.fox@ed.ac.uk

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
United Kingdom
W1H 6DH
+44 (0)20 7935 0185
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