ISRCTN57596739 https://doi.org/10.1186/ISRCTN57596739

Nitrites In Acute Myocardial Infarction trial

Submission date 29/09/2011	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 29/09/2011	**Overall study status** Completed	
Last Edited 19/03/2014	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2010-023571-26

Protocol serial number
9748

Study information

Scientific Title
Does sodium nitrite administration reduce ischaemia-reperfusion injury in patients presenting with acute ST segment elevation myocardial infarction?

Acronym
NIAMI

Study objectives
Does a 2.5 - 5 minute systemic intravenous injection of sodium nitrite administered immediately before opening of the infarct related artery result in significant reduction of ischaemia reperfusion injury in patients with first acute ST elevation myocardial infarction (MI)?

Where possible, written consent will be sought prior to the intervention. However in the emergency setting, verbal agreement will be sought from eligible patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
First MREC, 2 March 2011, ref:10/MRE00/83

Study design
Randomised; Interventional; Design type: Treatment

Primary study design
Interventional

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Cardiovascular Disease: Coronary Artery

Interventions
1. Treatment: sterile solution containing 70 micromol sodium nitrite dissolved in 5ml water injected intravenously over 2 and a half to 5 minutes
2. Placebo: sterile solution containing 0.9%w/v sodium chloride in 5ml water injected intravenously over 2 and a half to 5 minutes
3. The active treatment and placebo will look identical so that patients and clinical staff remain blind to the allocation
4. Followed up after 6 months

Intervention Type
Other

Phase
Phase II/III

Primary outcome(s)
The difference in final infarct size between sodium nitrite and placebo groups both measured using MRI between 10-14 days following the acute myocardial infarction and corrected for area at risk

Key secondary outcome(s))

1. Plasma creatine kinase and Troponin I for 72 hours post MI
2. LV ejection fraction measured by MRI between days 10-14
3. LV ejection fraction measured by MRI at 6 months
4. LV end systolic volume index

Completion date
31/01/2013

Eligibility

Key inclusion criteria
1. Men or women
2. Aged at least 18 years to 55 years
3. Presenting within 12 hours of the onset of chest pain who have ST segment elevation of more 1mm elevation in limb leads or 2mm elevation in two contiguous chest leads and for whom the clinical decision has been made to treat with primary PCI will be eligible for enrolment
4. Occlusion of the culprit related artery (TIMI grade 0 or TIMI grade 1) will also be required for inclusion
5. Eligible patients will be of North European descent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Historical or ECG evidence of previous myocardial infarction
2. Patients with prior coronary artery bypass grafting (CABG)
3. Prior revascularization procedure where this procedure (PCI) was performed in the same territory as the current infarct
4. Known or suspected pregnancy
5. Contra-indications to MRI
6. Patients with cardiac arrest or cardiogenic shock
7. Patients with left main coronary occlusion
8. Patients with known moderate to severe renal failure (estimated GFR < 30mls/min), or liver failure
9. Patients with prior thrombolysis for this event

Date of first enrolment
08/08/2011

Date of final enrolment
31/01/2013

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
Centre for Healthcare Randomised Trials (CHaRT)
Aberdeen
United Kingdom
AB25 2ZD

Sponsor information

Organisation
University of Aberdeen (UK)

ROR
https://ror.org/016476m91

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC) (UK), ref: G1001340

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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	14/05/2014		Yes	No
Protocol article	protocol	06/05/2013		Yes	No
HRA research summary			28/06/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes