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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

Study website
https://www.abdn.ac.uk/chart/niami

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2010-023571-26

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
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

Secondary outcome measures
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

Overall study start date
08/08/2011

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

Age group
Adult

Lower age limit
18 Years

Sex

Both

Target number of participants
Planned Sample Size: 200; UK Sample Size: 200

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
Scotland

United Kingdom

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

Sponsor information

Organisation
University of Aberdeen (UK)

Sponsor details
Research and Innovation
University Office,

King's College
Aberdeen
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United Kingdom
AB24 3FX
+44 (0)1224 272 000

Sponsor type
University/education

Website
http://www.abdn.ac.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, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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?
Protocol article	protocol	06/05/2013		Yes	No
Results article	results	14/05/2014		Yes	No
HRA research summary			28/06/2023	No	No