

# Nitrites In Acute Myocardial Infarction trial

<b>Submission date</b> 29/09/2011	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 29/09/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 19/03/2014	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

## 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

### Contact name

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### Contact details

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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  
Scotland  
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?
<a href="#">Protocol article</a>	protocol	06/05/2013		Yes	No
<a href="#">Results article</a>	results	14/05/2014		Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No