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A randomised, double-blind, placebo-controlled trial assessing the safety and efficacy of intracoronary NITRITE infusion during Acute Myocardial Infarction

Submission date
18/01/2013

Recruitment status
No longer recruiting

Registration date
23/01/2013

Overall study status
Completed

Last Edited
27/08/2019

Condition category
Circulatory System

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

EudraCT/CTIS number
2011-000721-77

IRAS number

ClinicalTrials.gov number
NCT01584453

Secondary identifying numbers
12117

Study information

Scientific Title
A randomised, double-blind, placebo-controlled trial assessing the safety and efficacy of intracoronary NITRITE infusion during Acute Myocardial Infarction

Acronym
NITRITE-AMI

Study objectives
Despite advances in the treatment of heart attacks such as reopening of the blocked artery (primary angioplasty), the complications and death rates from failure of the heart to pump adequately remain high. The size of the heart attack is the major determinant of these adverse outcomes. Whilst reopening the artery allows blood to flow to the area of the heart starved of oxygen, this process also causes damage itself (reperfusion injury) and increases the size of the heart attack.

It has been shown that nitrite protects against reperfusion injury in models of heart attack. We will therefore perform a trial to investigate whether during a heart attack, an infusion of nitrite into the damaged artery protects against reperfusion injury and reduces heart attack size.

More details can be found at: http://public.ukcrn.org.uk/Search/StudyDetail.aspx?StudyID=12117

Ethics approval required
Old ethics approval format

Ethics approval(s)
Committee:- NRES Committee London-West London, 08 November 2011, REC reference: 11/LO/1500

Study design
Randomised single centre double-blind placebo-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Topic: Cardiovascular; Subtopic: Cardiovascular (all Subtopics); Disease: Atherothrombosis

Interventions
Sodium Chloride, Placebo
10mls Intra-coronary at time of PPCI; Sodium Nitrite, Study IMP
10mls 1.8% intra-coronary during PPCI

The experimental intervention is a bolus of sodium nitrite solution (1.8 micromol in 10 ml (pre-diluted in 0.9% sodium chloride in a syringe) which will be delivered over 30 seconds via intracoronary injection initiated during the re-establishment of antegrade epicardial flow with PPCI.

The control intervention is a bolus of 0.9% sodium chloride solution (prepared with an identical appearance to the sodium nitrite).

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Creatine Kinase AUC first 48 hours after PPCI

Secondary outcome measures
1. Infarct size on CMR; Timepoint(s): 48 hours and 6 months
2. Myocardial salvage index (MSI) on CMR; Timepoint(s): 48 hours
3. Troponin T AUC; Timepoint(s): 1st 48 hours after PPCI

Overall study start date
10/04/2012

Completion date
10/02/2014

Eligibility

Key inclusion criteria
1. Patients aged at least 18 years, upper age limit 80 years, male and female
2. Acute ST-elevation myocardial infarction with ECG showing at least 2 mm of ST segment elevation in 2 or more limb leads or 1mm in 2 or more contiguous chest leads, or new left bundle branch block
3. Haemodynamically stable
4. Estimated symptom to balloon or aspiration time < 6 hours
5. A signed and dated written informed consent prior to admission to the study
6. Angiographicallly
6.1. Primary Percutaneous Coronary Intervention (PPCI) indicated for revascularisation

6.2. Single epicardial artery to be treated
6.3. Expected ability to use the over the wire balloon for delivery of nitrite

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
UK Sample Size: 80

Key exclusion criteria
1. Patients already on nitrate Treatment (Nicorandil, ISMN)
2. Previous history of myocardial infarction (MI) or systolic dysfunction
3. Previous coronary artery bypass surgery (CABG)
4. Subjects presenting with cardiogenic shock (SBP <80 mmHg for >30 minutes, or requiring inotropes or emergency IntraAortic
Balloon Pump (IABP) for hypotension treatment) or cardiopulmonary resuscitation
5. Current diagnosis of or treatment for malignancy, other than non-melanoma skin cancer
6. Current life-threatening condition other than vascular disease that may prevent a subject completing the study
7. Use of an investigational device or investigational drug within 30 days or 5 half-lives (whichever is the longer) preceding the first dose of study medication
8. Patients considered unsuitable to participate by the research team (e.g., due to medical reasons, laboratory abnormalities, or subjects unwillingness to comply with all study-related procedures)
9. Severe acute infection, or significant trauma (burns, fractures)
10. Pregnancy
11. Contraindications tocardiac magnetic resonance (CMR) scanning
11.1. Pacemakers, intracranial clips or other metal implants or foreign bodies
11.2. Claustrophobia
11.3. Renal Failure (eGFR<30mls/min)
12. History of alcohol or drug abuse within the past 6 months
13. History of congenital methaemoglobinaemia
14. Angiographically
14.1. Severe vessel tortuosity, diffuse disease or severe calcification is present which may impede successful delivery of the over the wire balloon

Date of first enrolment
10/04/2012

Date of final enrolment
10/02/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
London Chest Hospital
London
United Kingdom
E2 9JX

Sponsor information

Organisation
Barts and The London NHS Trust (UK)

Sponsor details
Joint Research Office
24-26 Walden Street
London
England
United Kingdom
E1 2AN

Sponsor type
Hospital/treatment centre

Website
http://www.bartsandthelondon.nhs.uk/

ROR
https://ror.org/00b31g692

Funder(s)

Funder type
Government

Funder Name
NIHR (UK) - Doctoral Research Fellowship; Grant Codes: NIHR-DRF-2011-04-080

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	02/04/2013		Yes	No
Results article	results	01/04/2017		Yes	No
Results article	results	30/01/2015	27/08/2019	Yes	No
HRA research summary			28/06/2023	No	No