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PICSO in NSTEMI

Submission date 04/02/2015	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 04/02/2015	**Overall study status** Completed	
Last Edited 16/03/2018	**Condition category** Circulatory System	

Plain English summary of protocol
Plain English summary under review

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
18107

Study information

Scientific Title

PICSO in NSTEMI registry: Pressure controlled intermittent coronary sinus occlusion in NonST elevation Myocardial Infarction

Study objectives
Aim of this study is to evaluate whether pressure controlled intermittent coronary sinus occlusion (PICSO) reduces the level of microvascular obstruction (MVO) in patients with acute NSTEMI, thereby reducing infarct size.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London - Stanmore Research Ethics Committee, 04/11/2014, ref: 14/LO/1365

Study design
Randomised; Interventional; Design type: Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

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

Interventions
Pressure controlled Intermittent Coronary Sinus Occlusion (PICSO)

Intervention Type
Procedure/Surgery

Primary outcome measure
Infarct Size reduction; Timepoint(s): Infarct Size reduction from days 35 after PCI to 4 months post PCI

Secondary outcome measures
Not provided at time of registration

Overall study start date
05/01/2015

Completion date
05/02/2016

Eligibility

Key inclusion criteria
1. Ischemic symptoms such as angina pectoris for more than 20 minutes
2. Occurrence of previous symptoms less than 72 hours before enrolment
3. Cardiac troponin levels above the 99th percentile at presentation and
4. Age range: 18-75

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
Planned Sample Size: 60; UK Sample Size: 60

Key exclusion criteria
1. Cardiogenic shock
2. STEMI
3. Coronary anatomy ineligible for Coronary Sinus cannulation.
4. Indication for acute bypass surgery
5. Pregnancy
6. Current participation in another study
7. Comorbidity with a life expectancy of less than 6 months
8. Contraindication to cMRI

Date of first enrolment
05/01/2015

Date of final enrolment
05/02/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Wycombe General Hospital
Queen Alexandra Road
High Wycombe
Buckinghamshire
United Kingdom
HP11 2TT

Sponsor information

Organisation
Buckinghamshire Healthcare NHS Trust

Sponsor details
Department of R&D
Stoke Mandeville Hospital
Mandeville Road
Aylesbury
England
United Kingdom
HP21 8AL

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/037f2xv36

Funder(s)

Funder type
Industry

Funder Name
Miracor Medical Systems GmbH (Austria)

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?
HRA research summary			28/06/2023	No	No