

PICSO in NSTEMI

Submission date 04/02/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 04/02/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 16/03/2018	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Plain English summary under review

Contact information

Type(s)

Scientific

Contact name

Mrs Nicola Bowers

Contact details

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

Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

75 years

Sex

All

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**

United Kingdom

England

Study participating centre**Wycombe General Hospital**

Queen Alexandra Road

High Wycombe

Buckinghamshire

United Kingdom

HP11 2TT

Sponsor information

Organisation

Buckinghamshire Healthcare NHS Trust

ROR

<https://ror.org/037f2xv36>

Funder(s)**Funder type**

Industry

Funder Name

Miracor Medical Systems GmbH (Austria)

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?
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes