

Investigation of the effect of InterLeukin-1 receptor Antagonist on markers of inflammation in non-ST elevation acute coronary syndromes

Submission date 10/08/2006	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 03/10/2006	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 26/10/2012	Condition category Circulatory System	☐ 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

Protocol serial number

101105

Study information

Scientific Title

Acronym

MRC-ILA-HEART study

Study objectives

Does treatment of Non-ST Elevation Myocardial Infarction (NSTEMI)/Acute Coronary Syndrome (ACS) with InterLeukin-1 receptor antagonist (IL-1ra) alter the inflammatory process involved in this condition?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Leeds (West) Research Ethics Committee, 18th December 2006, ref: 06/Q1205/234.

Primary study design

Interventional

Study design

Randomised double blind placebo controlled multi-centre phase II clinical trial.

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Non-ST elevation acute coronary syndromes

Interventions

Eligible patients will be randomised in equal proportions between IL-1ra and placebo, receiving either a once daily, subcutaneous (s.c.) injection of IL-1ra (dose 100 mg per 24 hours) for 14 days, or a daily s.c. injection of placebo for 14 days.

Intervention Type

Drug

Phase

Phase II

Drug/device/biological/vaccine name(s)

InterLeukin-1 receptor antagonist

Primary outcome(s)

Area under the curve of serum high sensitivity C-Reactive Protein (hsCRP) over the first seven days.

Key secondary outcome(s)

1. Mean hsCRP at seven, 14 and 30 days
2. Area under the curve of Troponin-I
3. von Willebrand Factor (vWF) and InterLeukin-6 (IL-6)
4. ST segment depression on Holter monitor
5. Myocardial injury as determined by Gadolinium enhanced Cardiovascular Magnetic Resonance (CMR) scan
6. Forearm endothelial cell response
7. Incidence of Major Adverse Cardiovascular Events (MACE) at 30 days, three months and at one year
8. Flagging with Office of National Statistics (ONS) for up to five years

Completion date

01/01/2009

Eligibility

Key inclusion criteria

1. Aged over 18 years of age
2. Acute severe cardiac chest pain consistent with an acute coronary syndrome
3. Less than 48 hours from onset of symptoms that led to hospital admissions
4. And at least one of the following:
 - a. Horizontal or down-sloping ST depression of at least 0.5mm in at least two Electrocardiogram (ECG) leads
 - b. a raised troponin as defined by local parameters specified at each centre
 - c. Other ECG changes consistent with acute myocardial ischaemia (e.g. T-wave inversion of at least 3 mm, in at least two leads of the ECG, or new onset bundle branch block) and an elevated level of Troponin above local laboratory values indicating myocardial damage

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. Less than 18 years of age
2. Persistent ST elevation on the presenting ECG
3. Intention to treat with an urgent reperfusion strategy (thrombolysis or primary percutaneous coronary intervention)
4. Percutaneous coronary intervention within previous three months
5. Previous coronary artery bypass grafting

6. ECG showing paced rhythm
7. Cardiogenic shock (as defined in the Trial Manual)
8. Any serious co-morbidity which makes it unlikely that the patient will complete trial procedures and follow-up
9. Treatment or under active follow-up for rheumatoid arthritis, other connective tissue diseases or inflammatory bowel disease
10. End stage renal disease or a Creatinine more than 220 µmol/L
11. Pregnancy or suspected pregnancy (any potential female participant of child bearing age will need a negative pregnancy test prior to study entry)
12. Eosinophilia
13. Anti-Tumour Necrotising Factor (TNF) biologics
14. Active infection
15. Malignancy

Date of first enrolment

01/01/2007

Date of final enrolment

01/01/2009

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Cardiovascular Research Unit

Sheffield

United Kingdom

S10 2RX

Sponsor information

Organisation

University of Sheffield (UK)

ROR

<https://ror.org/05krs5044>

Funder(s)

Funder type

Research council

Funder Name

Medical Research Council grant award (ref no: G0502131)

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?
Results article	results	25/02/2008		Yes	No