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

Submission date	Recruitment status	[X] Prospectively registered
10/08/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
03/10/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
26/10/2012	Circulatory System	

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

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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.

Study design
Randomised double blind placebo controlled multi-centre phase II clinical 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
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 measure
Area under the curve of serum high sensitivity C-Reactive Protein (hsCRP) over the first seven days.

Secondary outcome measures
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

Overall study start date
01/01/2007

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
186

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) biologies
14. Active infection
15. Malignancy

Date of first enrolment
01/01/2007

Date of final enrolment
01/01/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Cardiovascular Research Unit
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Sponsor information

Organisation
University of Sheffield (UK)

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Sponsor type
University/education

Website
http://www.shef.ac.uk/researchoffice/about

ROR
https://ror.org/05krs5044

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council grant award (ref no: G0502131)

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?
Results article	results	25/02/2008		Yes	No