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Characterisation of the cytokine response in the Acute Coronary Syndrome and its modulation with angiotensin-converting enzyme inhibition (Protocol B)

Submission date 12/09/2003	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 12/09/2003	**Overall study status** Completed	
Last Edited 16/08/2012	**Condition category** Circulatory System	

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
N0436121377

Study information

Scientific Title

Study objectives
To define the effects that angiotensin-converting enzyme inhibitors have on circulating levels of the pro-inflammatory cytokines; tumour necrosis factor (TNF)-alpha and interleukin-6 (IL-6), and the anti-inflammatory cytokine; IL-10.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Randomised active controlled parallel group trial

Study type(s)
Not Specified

Health condition(s) or problem(s) studied
Acute coronary syndrome

Interventions
Randomised controlled trial. Random allocation to:
1. Standard management
2. Standard management + angiotensin-converting enzyme inhibitor

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Cytokine levels measured in the blood peripheral venous blood

Key secondary outcome(s)
Not provided at time of registration

Completion date
31/10/2005

Eligibility

Key inclusion criteria

The patient population will be drawn from all patients admitted to the cardiac unit based at the Leeds General Infirmary or St James's University Hospital with chest pain within the preceding 24 h. Patients must have a history and electrocardiogram (ECG) changes consistent with a diagnosis of the Acute Coronary Syndrome.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Patients with ST elevation myocardial infarction

Date of first enrolment
31/10/2002

Date of final enrolment
31/10/2005

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Institute for Cardiovascular Research
Leeds
United Kingdom
LS1 3EX

Sponsor information

Organisation
Department of Health (UK)

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Leeds Teaching Hospitals NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration