

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
Registration date 12/09/2003	Overall study status Completed	☐ Protocol
Last Edited 16/08/2012	Condition category Circulatory System	☐ Statistical analysis plan
		☐ Results
		☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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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

Study design

Randomised active controlled parallel group trial

Primary study design

Interventional

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