ISRCTN51684951 https://doi.org/10.1186/ISRCTN51684951

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

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
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Not Specified

Participant information sheet

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 measure
Cytokine levels measured in the blood peripheral venous blood

Secondary outcome measures
Not provided at time of registration

Overall study start date
31/10/2002

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

Age group
Adult

Sex
Both

Target number of participants
Not provided at time of registration

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
England

United Kingdom

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

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Leeds Teaching Hospitals NHS Trust (UK)

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