

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

<b>Submission date</b> 12/09/2003	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 12/09/2003	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 16/08/2012	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Dr SY Ooi

### Contact details

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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