

The effect of myocardial ischaemia on pro-inflammatory cytokines and stress proteins

Submission date 12/09/2003	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 12/09/2003	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 09/08/2021	Condition category Circulatory System	<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

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Additional identifiers

Protocol serial number
N0016121116

Study information

Scientific Title

The effect of myocardial ischaemia on pro-inflammatory cytokines and stress proteins: a randomised controlled study

Study objectives

Are the cytokines elevated during stress?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Added 24 July 2008:

Approval granted by Hammersmith, Queen Charlotte's & Chelsea and Acton Hospital Research Ethics Committee.

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Not Specified

Health condition(s) or problem(s) studied

Cardiovascular: Myocardial ischaemia

Interventions

Treadmill Stress vs Pharmacological Stress (Dobutamine)

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Dobutamine

Primary outcome(s)

To assess the plasma levels of interleukin-6 (IL6), tumour necrosis factor alpha (TNFa), tissue factor (TF) and heat shock protein 60 (hsp60). Two stress methods will be employed. While IL6 can also be increased with peripheral muscle stress produced by exercise, dobutamine could induce a smaller ischaemic burden. The two tests therefore will be performed in each patient in order to link cytokines to ischaemia alone.

Key secondary outcome(s)

No secondary outcome measures

Completion date

10/09/2009

Eligibility

Key inclusion criteria

Added 24 July 2008:

Patients with greater than or equal to 1 flow-limiting coronary artery stenosis, stable symptoms & ST segment depression on exercise testing (if there is one prior to angiogram)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

Key exclusion criteria

Added 24 July 2008:

Control subjects with low pre-exercise test probability of CAD & negative exercise test result (age- / sex- / body mass index- matched).

Date of first enrolment

02/09/2002

Date of final enrolment

10/09/2009

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Echocardiology Department

London

United Kingdom

W12 0HS

Sponsor information

Organisation

Department of Health (UK)

Funder(s)**Funder type**

Government

Funder Name

Hammersmith Hospital NHS Trust (UK)

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration