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

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 09/08/2021	**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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Not Specified

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
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 perpheral 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.

Secondary outcome measures
No secondary outcome measures

Overall study start date
02/09/2002

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

Age group
Not Specified

Sex
Not Specified

Target number of participants
40

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
England

United Kingdom

Study participating centre
Echocardiology Department
London
United Kingdom
W12 0HS

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
Government

Funder Name
Hammersmith Hospital 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