# The effect of myocardial ischaemia on proinflammatory cytokines and stress proteins

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
12/09/2003	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
12/09/2003	Completed	Results
Last Edited	Condition category	[] Individual participant data
09/08/2021	Circulatory System	<ul><li>Record updated in last year</li></ul>

### Plain English summary of protocol

Not provided at time of registration

### Contact information

### Type(s)

Scientific

#### Contact name

Prof Petros Nihoyannopoulos

#### Contact details

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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