

# The effect of mental stress on the heart in patients with coronary artery disease. Part 1. A study of mechanisms that Predispose to abnormal heart rhythms. Part 2. A study of Management Using Relaxation Techniques.

<b>Submission date</b> 30/09/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 30/09/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 13/12/2013	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

**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**

N0277138953

## **Study information**

**Scientific Title**

### **Study objectives**

To test the hypothesis that in patients with abnormal coronary arteries, mental stress induces electrical instability in the heart not simply by a direct effect of increased sympathetic nerve activity on the heart, but by creating an oxygen supply/demand mismatch i.e. a low grade ischaemia, which is unrecognised both clinically and on the conventional electrocardiogram (ECG).

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Not provided at time of registration

### **Study design**

Randomised controlled trial

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Not specified

### **Study type(s)**

Not Specified

### **Participant information sheet**

### **Health condition(s) or problem(s) studied**

Cardiovascular: Coronary artery disease

### **Interventions**

Patients attending Cardiology Outpatients clinic will follow one of the 4 protocols.

1. They will either receive Glycerol trinitrite (commonly used for angina) or placebo tablets under the tongue and be connected to an electrocardiogram (ECG) recorder and given 2 mental stress tasks e.g. mental arithmetic of subtracting numbers as rapidly as possible in 5 minutes and

after 5 minutes rest make a 5 minute speech. The tests are repeated one week later but with the other tablet.

2. For patients taking Nicorandil, the same tests apply unless nicorandil is given before repeat test. Patient will need a third test without any tablets under tongue.

3. Patient will wear ECG recorder for 24 hours with 4 sticky probes attached to chest, whilst they go about everyday activities keeping a diary

4. In the Cardiology Outpatient Clinic the patient will be attached to the ECG and will have to recall 2 negative emotional experiences from the past and 2 positive experiences after a 5 minute rest. One group will be taught how to induce relaxation by self hypnosis.

### **Intervention Type**

Other

### **Phase**

Not Specified

### **Primary outcome measure**

Not provided at time of registration

### **Secondary outcome measures**

Not provided at time of registration

### **Overall study start date**

01/01/2004

### **Completion date**

05/12/2005

## **Eligibility**

### **Key inclusion criteria**

20 patients attending hospital for management of their coronary artery disease. 10 patients on medication with Nicorandil and 10 not receiving Nicorandil. Each group will attend the Cardiology Out Patient Dept by appointment on two occasions at weekly intervals for ECG.

### **Participant type(s)**

Patient

### **Age group**

Not Specified

### **Sex**

Not Specified

### **Target number of participants**

20

### **Key exclusion criteria**

Not provided at time of registration

**Date of first enrolment**

01/01/2004

**Date of final enrolment**

05/12/2005

## Locations

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

Clinic 3A

London

United Kingdom

N19 5NF

## Sponsor information

**Organisation**

Department of Health

**Sponsor details**

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

**Sponsor type**

Government

**Website**

<http://www.dh.gov.uk/Home/fs/en>

## Funder(s)

**Funder type**

Government

**Funder Name**

Whittington Hospital NHS Trust

## 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

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/01/2009		Yes	No