

# 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

**Protocol serial number**  
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

## Study type(s)

Not Specified

## 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(s)**

Not provided at time of registration

**Key secondary outcome(s)**

Not provided at time of registration

**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

**Healthy volunteers allowed**

No

**Age group**

Not Specified

**Sex**

Not Specified

**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**

United Kingdom

England

**Study participating centre**

Clinic 3A

London

United Kingdom  
N19 5NF

## Sponsor information

**Organisation**  
Department of Health

## Funder(s)

**Funder type**  
Government

**Funder Name**  
Whittington Hospital NHS Trust

## Results and Publications

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