

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.

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr D Patterson

Contact details
Clinic 3A
Diagnostic Block
Whittington Hospital
Highgate Hill
London
United Kingdom
N19 5NF
+44 (0)20 7272 5292
david.patterson@whittington.nhs.uk

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?
Results article	results	01/01/2009		Yes	No