Pilot study to test the usefulness of contractile reserve during dobutamine and exercise echo to predict recovery after mitral valve repair mitral valve prolapse

Submission date	Recruitment status	Prospectively registered
28/09/2007	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
28/09/2007	Completed	Results
Last Edited	Condition category	[] Individual participant data
24/08/2015	Circulatory System	Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Eastbourne District General Hospital
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Eastbourne
United Kingdom
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

Pilot study to test the usefulness of contractile reserve during dobutamine and exercise echo to predict recovery after mitral valve repair mitral valve prolapse

Study objectives

To assess usefulness of contractile reserve during dobutamine and exercise echo to predict recovery after mitral valve repair for mitral valve prolapse. Whether contractile reserve judged by stress echocardiography, both pharmacological and exercise, can accurately predict post-operative exercise performance as judged by metabolic exercise performance following valve repair for mitral valve prolapse.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled pilot study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

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: Mitral valve disease

Interventions

Dobutamine vs standard practice

Intervention Type

Drug

Phase

Drug/device/biological/vaccine name(s)

dobutamine

Primary outcome measure

Death, myocardial infarction, hospitalisation for CHF.

Secondary outcome measures

- 1. Baseline tissue Doppler contractile reserve
- 2. Baseline exercise test parameters
- 3. Neurohumoral markers
- 4. TOE and surgical parameters

Overall study start date

07/03/2007

Completion date

01/05/2007

Eligibility

Key inclusion criteria

- 1. Patients admitted to Eastbourne District General Hospital for mitral valve repair
- 2. Accepted for repair of mitral valve prolapse on clinical grounds and high probability of repairable valve

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

15

Key exclusion criteria

- 1. Inability to perform test
- 2. Hypersensitivity to dobutamine or SonoView

Date of first enrolment

07/03/2007

Date of final enrolment

01/05/2007

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Eastbourne District General Hospital
Eastbourne
United Kingdom
BN21 2UD

Sponsor information

Organisation

Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Sponsor details

The Department of Health Richmond House 79 Whitehall London United Kingdom SW1A 2NL +44 (0)20 7307 2622 dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

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

Funder(s)

Funder type

Government

Funder Name

East Sussex Hospitals NHS Trust (UK), Peer Medical Research Trust

Results and Publications

Publication and dissemination planNot provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summaryNot provided at time of registration