

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

<b>Submission date</b> 28/09/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 28/09/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 24/08/2015	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Dr Guy Lloyd

### Contact details

Cardiology Department  
Eastbourne District General Hospital  
Kings Drive  
Eastbourne  
United Kingdom  
BN21 2UD

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0019189543

## 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

Not Specified

**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 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