ISRCTN14627513 https://doi.org/10.1186/ISRCTN14627513

# 'AQURO', a new, potentially automatable approach for quatifying mitral regurgitation: technology development and validation through collaboration between cardiovascular science and bioengineering

Submission date 18/06/2010	<b>Recruitment status</b> No longer recruiting	Prospectively registered	
		[_] Protocol	
<b>Registration date</b> 18/06/2010	<b>Overall study status</b> Completed	[] Statistical analysis plan	
		[X] Results	
Last Edited 27/08/2014	<b>Condition category</b> Circulatory System	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 7355

## Study information

Scientific Title

Acronym DRN 373 (AQURO)

### **Study objectives**

Stable subjects with mitral regurgitation previously diagnosed on echocardiography will be recruited from the outpatient service of Imperial College Healthcare NHS Trust. We will follow the standard British Society of Echocardiography protocol, and then add additional views. The standard protocol involves ultrasound recordings in different positions around the heart. Each complete echocardiography appointment will take approximately 40 minutes. All calculations made from the recorded images will occur later, after the patient has left.

**Ethics approval required** Old ethics approval format

Ethics approval(s) MREC approved (ref: 08/H0707/71)

**Study design** Single-centre non-randomised interventional diagnosis trial

**Primary study design** Interventional

**Secondary study design** Non randomised controlled trial

**Study setting(s)** Hospital

**Study type(s)** Diagnostic

Participant information sheet

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

Topic: Diabetes Research Network; Subtopic: Type 2; Disease: Cardiovascular disease

#### Interventions

Patients are recruited and ultrasound scans are performed for about 40 minutes to be analysed and compared with the standard technique.

Study entry: registration only

**Intervention Type** Other

**Phase** Not Applicable

**Primary outcome measure** Effective regurgitant orifice area (EROA), measured during 40 minutes of acquisition

**Secondary outcome measures** Not provided at time of registration

Overall study start date 23/03/2009

Completion date 23/03/2012

## Eligibility

**Key inclusion criteria** Stable subjects with mitral regurgitation previously diagnosed on echocardiography

Participant type(s) Patient

Age group Not Specified

**Sex** Not Specified

**Target number of participants** Planned sample size: 50; UK sample size: 50

### Key exclusion criteria

1. Atrial fibrillation

2. Moderate or severe disease of tricuspid or pulmonary valves

3. Any aortic valve disease graded mild or higher

4. Prosthetic aortic valve and body habitus or coexistent disease that precludes satisfactory imaging quality

Date of first enrolment

23/03/2009

### Date of final enrolment

23/03/2012

## Locations

**Countries of recruitment** England

United Kingdom

**Study participating centre St Mary's Hospital** London United Kingdom W2 1NY

## Sponsor information

**Organisation** Imperial College Healthcare NHS Trust (UK)

**Sponsor details** International Centre for Circulatory Health 59 North Wharf Road London England United Kingdom W2 1LA

**Sponsor type** Hospital/treatment centre

Website http://www.imperial.nhs.uk/

ROR https://ror.org/056ffv270

## Funder(s)

**Funder type** Charity

**Funder Name** British Heart Foundation (BHF) (UK) Alternative Name(s) the\_bhf, The British Heart Foundation, BHF

**Funding Body Type** Private sector organisation

#### **Funding Body Subtype** Trusts, charities, foundations (both public and private)

**Location** United Kingdom

## **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	01/07/2013		Yes	No