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'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	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 18/06/2010	**Overall study status** Completed	
Last Edited 27/08/2014	**Condition category** Circulatory System	

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