

Targeted left ventricular lead placement in cardiac resynchronisation therapy

Submission date 01/09/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 08/02/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 19/06/2012	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 David Dutka

Contact details
Level 6 ACCI Building
Addenbrooke's Hospital
Hills Road
Cambridge
United Kingdom
CB2 2QQ

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1.0

Study information

Scientific Title

TARgeted left ventricular lead placement to Guide cardiac rEsynchronisation Therapy in patients with heart failure: a randomised prospective study (TARGET Study)

Acronym

TARGET Study

Study objectives

The clinical response to cardiac resynchronisation therapy will be improved by optimising the site of left ventricular (LV) pacing using a targeted approach to optimal sites defined by pre-implant speckle tracking 2D radial strain as the latest contracting segments.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Hertfordshire Research Ethics Committee approved on the 14th October 2008 (ref: 08/H0311/133)

Study design

Prospective randomised controlled trial

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 contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Cardiovascular disease/heart failure/device therapy

Interventions

All patients scheduled for CRT who are suitable candidates are randomised into one of two groups. All patients have baseline tests to include echocardiography, NYHA class assessment, 6-minute walk test, QoL score and speckle tracking echocardiography (STE). At implant, the control group has a usual implant and the target group has the device implanted using echo guidance. All patients are followed up again at 6 months with a repeat of the baseline tests.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Response to treatment defined as greater than 15% reduction in Left Ventricular End Systolic Volume at 6 months follow up

Secondary outcome measures

Clinical Improvement in combined endpoint of 6 minute walk test performance, Minnesota Living with Heart Failure Questionnaire and NYHA Class

Overall study start date

01/04/2009

Completion date

01/10/2011

Eligibility**Key inclusion criteria**

1. Patients (aged 18 years or older, either sex) limited by symptoms of heart failure (New York Heart Association Class III - IV)
2. Left ventricular ejection fraction (LVEF) of less than or equal to 35% and QRS width of greater than or equal to 120 ms despite maximally tolerated doses of standard heart failure treatment (diuretics, angiotensin converting enzyme (ACE) inhibitors, angiotensin receptor blockers, beta blockers and aldosterone antagonists)

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

220 (110 in each arm)

Key exclusion criteria

1. Limiting angina
2. Myocardial infarction within preceding 3 months
3. Significant LV hypertrophy
4. Severe co-morbid illness

Date of first enrolment

01/04/2009

Date of final enrolment

01/10/2011

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Level 6 ACCI Building

Cambridge

United Kingdom

CB2 2QQ

Sponsor information

Organisation

Papworth Hospital NHS Foundation Trust (UK)

Sponsor details

R&D Department

Papworth Hospital

Cambridge

England

United Kingdom

CB23 8RE

Sponsor type

Hospital/treatment centre

Website

<http://www.papworthhospital.nhs.uk/>

ROR

<https://ror.org/01qbabb31>

Funder(s)

Funder type

Research council

Funder Name

Biomedical Research Council (BMRC) (UK)

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	24/04/2012		Yes	No