

Targeted left ventricular lead placement in cardiac resynchronisation therapy

Submission date 01/09/2010	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 08/02/2011	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 19/06/2012	Condition category 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

Protocol serial number
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)

Primary study design

Interventional

Study design

Prospective randomised controlled trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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

United Kingdom

England

Study participating centre

Level 6 ACCI Building
Cambridge
United Kingdom
CB2 2QQ

Sponsor information

Organisation

Papworth Hospital NHS Foundation Trust (UK)

ROR

<https://ror.org/01qbebb31>

Funder(s)

Funder type

Research council

Funder Name

Biomedical Research Council (BMRC) (UK)

Results and Publications

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