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Targeted left ventricular lead placement in cardiac resynchronisation therapy

Submission date	Recruitment status	[_] Prospectively registered
01/09/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
08/02/2011	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
19/06/2012	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
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
Cardiovascualr disease/heart failure/device therapy

Interventions
All patients schedules 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 training echocardiography (STE). At implant, the control group has a usual implant and the target group has the devide 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/01qbebb31

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