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Prediction of clinical improvement following biventricular pacing in patients with end-stage heart failure using tissue doppler echocardiography

Submission date 26/02/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 26/02/2007	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 14/10/2008	**Condition category** Circulatory System	[_] Individual participant data [_] Record updated in last year

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
NTR482

Study information

Scientific Title

Study objectives
In patients with end-stage heart failure (New York Heart Association [NYHA] class III or IV, left ventricular ejection fraction [LVEF] less than 35%, QRS duration more than 120 ms, left bundle branch block [LBBB]), the dyssynchrony of the left ventricle is the most important predictor of clinical benefit. The dyssynchrony of the left ventricle can be assessed (at any time before implantation) non-invasively by tissue doppler imaging (TDI). Thus, information on dyssynchrony derived from TDI may predict clinical benefit from bi-ventricular pacing (BVP).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Non-randomised, non-controlled, clinical trial

Primary study design
Interventional

Secondary study design
Single-centre

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet

Health condition(s) or problem(s) studied
Heart disease, heart failure

Interventions
Patients will undergo BVP implantation based on traditional selection criteria. Maximal oxygen uptake (VO2 max) and TDI will be performed before and three months after BVP implantation. From these patients the TDI criteria which optimally predict clinical improvement (in VO2 max) will be derived.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
To develop non-invasive selection criteria (using echocardiography) to identify patients with end-stage heart failure who are likely to benefit from biventricular pacing.

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/05/2003

Completion date
01/05/2007

Eligibility

Key inclusion criteria
1. Severe heart failure (NYHA class III or IV)
2. Severely depressed LVEF less than 35%
3. QRS exhibiting left bundle branch block configuration with a duration greater than 120 ms

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
60

Key exclusion criteria
Does not comply with the above inclusion criteria

Date of first enrolment
01/05/2003

Date of final enrolment
01/05/2007

Locations

Countries of recruitment
Netherlands

Study participating centre
Leiden University Medical Centre (LUMC)
Leiden
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2300 RC

Sponsor information

Organisation
Leiden University Medical Centre (LUMC) (The Netherlands)

Sponsor details
Department of Cardiology
P.O. Box 9600
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Sponsor type
Hospital/treatment centre

Website
http://www.lumc.nl/english/start_english.html

ROR
https://ror.org/027bh9e22

Funder(s)

Funder type
Charity

Funder Name
Netherlands Heart Foundation (Nederlandse Hartstichting) (NHS) (The Netherlands)

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