

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	<input type="checkbox"/> Prospectively registered
Registration date 26/02/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 14/10/2008	Condition category Circulatory System	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

Protocol serial number

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

Study type(s)

Screening

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(s)

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

Key secondary outcome(s))

No secondary outcome measures

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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

Netherlands

2300 RC

Sponsor information

Organisation

Leiden University Medical Centre (LUMC) (The Netherlands)

ROR

<https://ror.org/027bh9e22>

Funder(s)

Funder type

Charity

Funder Name

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

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration