Left Bundle Branch Pacing Versus Coronary Sinus Pacing for Cardiac Resynchronization Therapy.

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The study will investigate the feasibility of using direct left bundle branch pacing (LBB pacing) as an alternative to biventricular pacing in patients with symptomatic heart failure and an ECG with a typical left bundle branch block pattern. The...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Heart failures
Study type	Interventional

Summary

ID

NL-OMON49994

Source
ToetsingOnline

Brief title
LBB-SYNC trial

Condition

- Heart failures

Synonym
cardiomyopathy, congestive heart failure

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis
Source(s) of monetary or material Support: Research & Development afdeling van Catharina Hartcentrum

Intervention

Keyword: Cardiac resynchronzation therapy, Left bundle branch pacing, Physiologic pacing

Outcome measures

Primary outcome

Success rate for implantation of LBB electrode.

Secondary outcome

Secondary endpoints (LBB pacing versus biventricular pacing - calculated both as intention-to-treat and per-protocol):

- Echocardiographic response after 6 months defined as decrease in left ventricular systolic diameter of >= 15% of baseline

- Echocardiographic response assessed by chamber dimensions and LVEF on a continuous scale

- Symptomatic response after 6 months defined as a fall in NYHA class of >= 1

- Improvement in well-being after 6 months defined as a decrease in Minnesota Living With Heart Failure score of >= 15% of baseline.

- Shortening the duration of the QRS complex defined as the widest paced QRS complex rated at 12-lead ECG after 6 months.

- Decline in NT-pro BNP value.

- Device-related complications:

*Periprocedural: CS/LBB electrode reoperation, pneumothorax, hemothorax, pericardial bleeding/tamponade.

*One month postoperative: CS/LBB electrode reoperation, phrenic nerve stimulation, infection requiring extraction.

Study description

Background summary

Biventricular pacing has for more than a decade been standard of care for patients with low ejection fraction (<35%), symptomatic heart failure despite optimal medical treatment and an ECG with left bundle branch block (LBBB). However, it is not always feasible because of several drawbacks such as phrenic nerve capture or inability to reach the target LV-lead location due to suboptimal anatomy of the venous coronary system. Physiologic pacing by directly capturing the left bundle and providing synchronous electrical activation of the left ventricle can overcome the aforementioned drawbacks of the conventional treatment.
In the present study we randomize patients to either conventional CRT or LBB pacing in a 1:1 open, non-blinded design. In the LBB pacing arm, direct LBB pacing is attempted but if it*s not possible due to technical difficulties, we will switch to conventional LV-lead placement.

Study objective

The study will investigate the feasibility of using direct left bundle branch pacing (LBB pacing) as an alternative to biventricular pacing in patients with symptomatic heart failure and an ECG with a typical left bundle branch block pattern. The primary endpoint of the study is the success rate of electrode implantation for direct LBB pacing in a patient group with disease in the cardiac conduction system as a major contributor to heart failure. If the study shows that LBB pacing is a possible alternative to biventricular pacing, it may pave the way for a larger national study.

Study design

The study is an open, single-center study. A total of 50 patients are expected to be randomized to 1:1 for conventional biventricular pacing (25 participants) or LBB-pacing (25 participants) and followed for 6 months.

Intervention

Implantation of LBB electrode.

Study burden and risks

Preoperative examinations and follow-up for both groups are similar. The biggest possible drawback for patients will be a longer implantation time if it is not possible to place the LBB pacing lead where we have to switch to the conventional procedure. Procedure time may take approximately 30 minutes longer

if LBB-lead placement is not successful and a switch to the conventional treatment is necessary.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

-Age 18+
-Ischemic or non-ischemic cardiomyopathy with LVEF <= 35% assessed by echocardiography,
-NYHA class II-IV heart failure symptoms despite optimal medical treatment
-Either planned new implantation of a biventricular pacing system (CRT-P or CRT-D), where ECG is with sinus rhythm and a typical left bundle branch block
-Or planned upgrade of existing biventricular pacing system (CRT-P or CRT-D) pacing system, where ECG is with sinus rhythm and typical left bundle branch

block or there has been> 90% right ventricular pacing from an existing pacemaker

Exclusion criteria

- Existing biventricular pacing system
- Permanent atrial fibrillation
- AMI or CABG within the last three months

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	50
Type:	Anticipated

Ethics review

Approved WMO Date:	14-01-2021
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL74343.100.20