Permanent left ventricular septal pacing versus right ventricular pacing in patients with atrioventricular conduction disorders: a randomized trial: LEAP trial

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28779

Source
NTR

Brief title
LEAP trial

Health condition

Cardiac Pacing
Pacing-Induced Cardiomyopathy
Conduction System Pacing
Left Ventricular Septal Pacing
Atrioventricular Block

Sponsors and support

Primary sponsor: Maastricht University
Source(s) of monetary or material Support: ZonMW Doelmatigheidsonderzoek

Intervention

Outcome measures

Primary outcome

The primary endpoint is a composite of all-cause mortality, hospitalization for heart failure, and a more than 10% decrease in left ventricular ejection fraction (LVEF) in absolute terms leading to a LVEF below 50%, which as a binary combined endpoint will be determined at one year follow-up.

Secondary outcome

- Time to first occurrence of all cause mortality or hospitalization for heart failure.
- Time to first occurrence of all cause mortality.
- Time to first occurrence of hospitalization for heart failure.
- Time to first occurrence of atrial fibrillation (AF) de novo.
- The echocardiographic changes in LVEF at one year.
- The echocardiographic changes in diastolic (dys-)function at one year.
- The occurrence of pacemaker related complications.
- Quality of life (QOL), cost-effectiveness analyses (CEA) and budget impact analysis (BIA).

The secondary endpoints (other than echocardiographic LVEF change) will be determined at the end of the follow-up period, when the last included patient has reached one year follow-up. The individual follow-up time for patients at this time point will vary with a minimum of one year.

Study description

Background summary

Rationale
Permanent cardiac pacing is the only available therapy in patients with atrioventricular (AV) conduction disorders and can be life-saving. Right ventricular pacing (RVP), the routine clinical practice for decades in these patients, is non-physiologic, leads to dyssynchronous electrical and mechanical activation of the ventricles, and may cause pacing-induced cardiomyopathy and heart failure.
Left ventricular septal pacing (LVSP) is an emerging form of physiologic pacing that can possibly overcome the adverse effects of RVP.

Study design and hypotheses
The LEAP trial is a multi-center investigator-initiated, prospective, randomized controlled, open label, blinded endpoint evaluation (PROBE) study that compares LVSP with conventional RVP. A total of 470 patients with a class I or IIa indication for pacemaker implantation due to AV conduction disorders and an expected ventricular pacing percentage >20% will be randomized 1:1 to LVSP or RVP. The primary endpoint is a composite endpoint of all-cause mortality, hospitalization for heart failure and a more than 10% decrease in left ventricular

ejection fraction (LVEF) in absolute terms leading to a LVEF below 50% at one year follow-up. LVSP is anticipated to result in improved outcomes.
Secondary objectives are to evaluate whether LVSP is cost-effective and associated with an improved quality of life (QOL) as compared to RVP. Quality of life is expected to improve with LVSP and reduced healthcare resource utilizations are expected to ensure lower costs in the LVSP group during follow-up, despite initial higher costs of the implantation.

Study objective

Left ventricular septal pacing is anticipated to result in improved outcomes regarding the primary and secondary endpoints.

Study design

1. Inclusion
2. Pacemaker implantation
3. 1 day post-implantation: PM check-up, assessment AE
4. 1 month: PM check-up, assessment AE
5. 6 months: PM check-up, outpatient clinic visit, questionnaires, assessment AE
6. 12 months: PM check-up, echocardiography, outpatient clinic visit, questionnaires, assessment AE
7. Every 6 months: PM check-up, outpatient clinic visit, questionnaires, assessment AE

The individual follow-up time will vary with a minimum of 1 year. The primary endpoint will be determined at 1 year follow-up. Secondary endpoints (except from echocardiographic parameters) will be determined at the end of the follow-up period.

Intervention

Experimental intervention:
Left ventricular septal pacing
Implantation of a pacemaker with the ventricular lead delivered transvenously through the interventricular septum (IVS) to the left ventricular (LV) septum.
Active comparator:
Right ventricular pacing
Implantation of a pacemaker with the ventricular lead placed in the RV.

Contacts

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Eligibility criteria

Inclusion criteria

• Age > 18y
• Life expectancy with good functional status of > 1y
• Class I or IIa pacemaker indication due to an atrioventricular conduction disorder
o Acquired 3rd or 2nd degree AVB
o Atrial arrhythmia with slow ventricular conduction
• Expected ventricular pacing percentage > 20%
• LVEF >35%
• Signed and dated informed consent form

Exclusion criteria

• Heart failure NYHA class III-IV
• Class I indication for CRT
• Class I indication for ICD
• Previous implanted CIED (except for ILR)
• Atrial arrhythmia with planned AV junction ablation
• PCI or CABG <30 days before enrollment
• Valvular heart disease with indication for valve repair or replacement
• Hypertrophic cardiomyopathy with interventricular septal thickness > 2 cm
• Renal insufficiency requiring hemodialysis
• Active infectious disease or malignancy
• Pregnancy

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-05-2021
Enrollment:	470
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	17-08-2021
Application type:	First submission

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
NTR-new	NL9672
Other	METC Azm/UM : METC 20-029

Study results