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

Gepubliceerd: 17-08-2021 Laatst bijgewerkt: 18-08-2022

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28779

Bron
Nationaal Trial Register

Verkorte titel
LEAP trial

Aandoening

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

Ondersteuning

Primaire sponsor: Maastricht University
Overige ondersteuning: ZonMW Doelmatigheidsonderzoek

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• 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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-05-2021
Aantal proefpersonen:	470
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	17-08-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9672
Ander register	METC Azm/UM : METC 20-029

Resultaten