Advanced Image Supported Lead Placement in Cardiac Resynchronization Therapy

Gepubliceerd: 26-05-2020 Laatst bijgewerkt: 15-05-2024

Primary Outcome: Targeted LV lead delivery results in a higher proportion of in-target pacing when compared to the control group. Secondary Outcomes: Targeted LV lead delivery results in more clinical benefit when compared to the control group.

Ethische beoordeling	Niet van toepassing
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON29327

Bron
NTR

Verkorte titel
ADVISE

Aandoening

Chronic heart failure with a reduced ejection fraction and dyssynchrony

Ondersteuning

Primaire sponsor: University Medical Center Utrecht
Overige ondersteuning: ZonMW, CART-Tech B.V.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Differences in % of patients with succesfull LV lead location between intervention and control group.

Toelichting onderzoek

Achtergrond van het onderzoek

Cardiac resynchronization therapy (CRT) is an established pacemaker therapy for patients with symptomatic chronic heart failure, but is hampered by a non-response rate of 30-40%. Optimising left ventricular lead placement is the cornerstone of improving treatment. The optimal location for the lead is remote from scar but within segments demonstrating late electromechanical activation. The present study aims to investigate the efficacy and clinical effect of the use of real-time guided lead placement using cardiac MRI and fluroscopy in a blinded, multicenter, randomized controlled trial.

Doel van het onderzoek

Primary Outcome: Targeted LV lead delivery results in a higher proportion of in-target pacing when compared to the control group.

Secondary Outcomes: Targeted LV lead delivery results in more clinical benefit when compared to the control group.

Onderzoeksopzet

Timepoint 1 (pre-implantation): ECG, NYHA, CMR and echocardiography
Timepoint 2 (during implantation): Guided or conventional CRT implantation
Timepoint 3 (follow-up at 6 months): ECG, NYHA, echocardiography
Timepoint 4 (one and two years): long-term clinical outcome and quality of life

Onderzoeksproduct en/of interventie

Real-time cardiac Magnetic Resonance-guided lead implantation by CARTBox.

Contactpersonen

Publiek

UMC Utrecht
Philippe Wouters

+31 88 75 743 75

Wetenschappelijk

UMC Utrecht
Philippe Wouters

+31 88 75 743 75

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Heart failure with LV ejection fraction ≤ 35%;
- New York Heart Association class II, III, or IV (ambulatory);
- Optimal medical treatment that is tolerable;
- Left bundle branch block (LBBB) and QRS ≥ 130 ms, OR non-LBBB and QRS ≥ 150 ms.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Contraindications for implantation of a CRT device;
- Age <18 years or incapacitated adult;
- Pregnancy or lactation
- Subjects with impaired renal function (severe renal insufficiency, GFR < 30 ml/min/1.73m2);
- Atrial fibrillation or atrial fibrillation during MRI
- Documented allergic reaction to gadolinium;
- Impossibility to undergo an MRI scan
- Participation in another clinical study that prohibits any procedures other than standard.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd

Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	08-02-2021
Aantal proefpersonen:	130
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Toelichting
Within legal and ethical limits, deidentified individual clinical trial participant-level data (IPD), generated by our research, can be made available. Upon publication, data will be made available upon reasonable request and in agreement with a collaboration agreement. A data sharing and management plan is provided.

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 54061
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8666
CCMO	NL73416.041.20
OMON	NL-OMON54061

Resultaten

Samenvatting resultaten

For previous work, please see Salden OAE et al. Multimodality imaging for real-time image-guided left ventricular lead placement during cardiac resynchronization therapy implantations. 2019. Int J Cardiovasc Imaging. 2019 Jul;35(7):1327-1337.