

Advanced Image Supported Lead Placement in Cardiac Resynchronization Therapy: feasibility in a multicentre setting

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1. Targeted LV-lead delivery is safe and feasible in a multicenter setting. 2. Image-registration using 2D fluoroscopy is non-inferior compared to standard 3D image registration (validation in first five patients). 3. Targeted LV-lead delivery will...

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

Samenvatting

ID

NL-OMON23393

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: UMC Utrecht

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Feasibility as assessed by the following feasibility criteria:

- Time to perform the placement of the LV lead
- Overall CRT implantation procedure duration
- Number of LV lead repositioning procedures.

Validation of the accuracy of 2D image registration compared to standard 3D image registration (in five patients).

- Procedural efficiency scored by the implanting cardiologist

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 feasibility of the use of real-time guided lead placement using cardiac MRI and fluroscopy in a multicentre setting.

Doel van het onderzoek

1. Targeted LV-lead delivery is safe and feasible in a multicenter setting.
2. Image-registration using 2D fluroscopy is non-inferior compared to standard 3D image registration (validation in first five patients).
3. Targeted LV-lead delivery will increase the proportion of responders, as compared to historic percentage of responders (60-70%).

Onderzoeksopzet

Timepoint 1: Pre-implantation CMR and echocardiography

Timepoint 2: Guided CRT implantation

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Capacitated adult patients referred for CRT with a class 1 or 2a indication for CRT according to the 2016 European Society of Cardiology Guidelines for the diagnosis and treatment of acute and chronic heart failure.

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 or contrast agent;
- Impossibility to undergo an MRI scan
- Participation in another clinical study that prohibits any procedures other than standard.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	12-09-2019
Aantal proefpersonen:	30
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies	
Datum:	03-04-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 49313
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8506
CCMO	NL67885.041.19
OMON	NL-OMON49313

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.