

Optimalisatie van pulmonaal venen isolatie door 'grid' visualisatie

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Freedom of atrial fibrillation (AF) after pulmonary vein isolation (PVI) is limited to 50-80% of patients, dependent on patient characteristics. This is typically due to electrical reconnection between the pulmonary veins and the left atrium at...

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

Samenvatting

ID

NL-OMON25776

Bron

NTR

Verkorte titel

Optigrid

Aandoening

Atrial Fibrillation, atriumfibrilleren, boezemfibrilleren

Ondersteuning

Primaire sponsor: VU University Medical Center

Overige ondersteuning: Biosense Webster

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Procedure time

Toelichting onderzoek

Achtergrond van het onderzoek

Randomized prospective intervention study, comparing grid visualization to point-by-point visualization of ablation lesions during pulmonary vein isolation.

Doel van het onderzoek

Freedom of atrial fibrillation (AF) after pulmonary vein isolation (PVI) is limited to 50-80% of patients, dependent on patient characteristics. This is typically due to electrical reconnection between the pulmonary veins and the left atrium at follow-up. Efforts to optimize outcome of catheter ablation for AF should therefore be directed towards creation of complete and lasting lesion circles.

The Carto 3D mapping system allows 3D visualisation of a cardiac chamber by fast anatomical mapping using intracardiac catheters. During PVI, an outline ('shell') of the left atrium is created on which the location of ablation can be manually annotated.

The new 'Visitag' module of the Carto 3D mapping system allows automated visualization of the precise site of ablation using a grid that is displayed on the 3D shell of the mapped cardiac chamber. In addition, it shows the amount of radiofrequency (RF) time for each specific grid point. Displaying the grid may provide a superior visual feedback for the operator on continuity of ablation lines and stability of the catheter, compared to single dot visualization by manual or automatic tagging. As a result it may improve procedure times and outcomes of catheter ablation of atrial fibrillation.

Onderzoeksopzet

1 year - freedom from atrial fibrillation

Onderzoeksproduct en/of interventie

Patients will be randomized to either encircling pulmonary veins using the automated point-by-point annotation (ablation index) or encircling pulmonary veins using the grid annotation.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

All patients (> 18 years) eligible for PVI according to ESC guidelines.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Unwilling or unable to give written informed consent

Prior left atrial surgery

Hyperthyroidism (treated hyperthyroidism in euthyriodic state is not an exclusion criterion)

Untreated or uncontrolled hypertension (systolic RR > 160 mmHg)

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blinding:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland
Status: Werving nog niet gestart
(Verwachte) startdatum: 01-03-2018
Aantal proefpersonen: 88
Type: Verwachte startdatum

Ethische beoordeling

Positief advies
Datum: 06-02-2018
Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 46613
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7162
NTR-old	NTR7361
CCMO	NL63859.029.18
OMON	NL-OMON46613

Resultaten