An MRI-validated study of Electrical Coupling Index catheter superiority in AF ablation – pre study

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DE-MRI is feasible to assess lesion size, transmurality and completeness of PVI. The study will be performed to determine if and how DE-MRI can be used in a larger subsequent multicentre trial (MERCI-AF study).

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

Samenvatting

ID

NL-OMON28416

Bron
Nationaal Trial Register

Verkorte titel
Merci-AF pre study

Aandoening

Atrial Fibrillation
DE-MRI
Ablation

Ondersteuning

Primaire sponsor: Medisch Spectrum Twente Enschede
Overige ondersteuning: Initiator = sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

To perform a pre-study to assess the feasibility of DE-MRI to assess lesion size, transmurality and completeness of PVI. The study will be performed to determine if and how DE-MRI can be used in a subsequent multicentre study (MERCI-AF study).

Toelichting onderzoek

Achtergrond van het onderzoek

Radiofrequency (RF) pulmonary vein isolation (PVI) represents an established therapy for treating atrial fibrillation (AF). The quality of catheter tip-to-tissue contact plays a critical role in ablation safety and efficacy. Catheters providing feedback on this tip-to-tissue contact have recently become available. Effectiveness of RF ablation by these catheters has recently been demonstrated in humans 1–3. MRI has shown to be of great value in assessing lesion size and transmurality in-vivo. To demonstrate the superiority of using the ECI catheters to conventional catheters for the effectiveness of AF ablation, post procedural MRI with delayed enhancement (DE-MRI) can possibly assess lesion size, transmurality of the lesion and completeness of PVI and relate this to clinical outcome.

Doel van het onderzoek

DE-MRI is feasible to assess lesion size, transmurality and completeness of PVI. The study will be performed to determine if and how DE-MRI can be used in a larger subsequent multicentre trial (MERCI-AF study).

Onderzoeksopzet

After 10 patients

Onderzoeksproduct en/of interventie

PVI using electrical coupling information (one side of PV's) or using no celectrical coupling information (other side of PV's)

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

• Paroxysmal atrial fibrillation for which ≥ 1 electrical and/or chemical cardioversions and persistent atrial fibrillation, eligible for PVI according to current international guidelines.

• Age < 70 years.

• Willing and able to sign informed consent.

• Willing to and capable of following the requested study procedures.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A potential subject who meets any of the following criteria will be excluded from participation in this study:

• Age < 18 years.

• Pregnancy

• Life or follow-up expectancy < 12 months.

• Previous PVI in history.

• Contrast allergy.

• Creatin clearance level lower than 60.

• MRI scanning not possible (e.g. because of metal implant or claustrophobia).

• Unsuccessful PVI during first procedure, while already in study. This will lead to exclusion after randomisation.

• Abnormal left atrium anatomy defined as number of PV's ≠ 4 . This will lead to exclusion after inclusion but before randomisation.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-03-2014
Aantal proefpersonen:	10
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

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	NL4116
NTR-old	NTR4357
Ander register	:
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten

N/A