

Usefulness of micro TEE and mini TEE imaging for EP procedures

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micro TEE and mini TEE can view the same required anatomical features as ICE for atrial transseptal puncture guidance.

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

Samenvatting

ID

NL-OMON25982

Bron

NTR

Aandoening

atrial fibrillation, ablation, EP procedures

Ondersteuning

Primaire sponsor: Philips Healthcare, Best, the Netherlands

Overige ondersteuning: Philips Healthcare, Best, the Netherlands

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The comparison of micro and mini TEE imaging compared with regular ICE imaging. The off line analysis of the data will allow the study team (treating physicians with support of Philips study team members) to evaluate the image quality compared to ICE imaging in atrial transseptal puncture during AF ablation procedures.

Toelichting onderzoek

Achtergrond van het onderzoek

Percutaneous catheter ablation of atrial fibrillation (AF) is a complex electrophysiological procedure, requiring good understanding of the cardiac anatomy and access to the left atrium (LA) which is obtained by transseptal puncture.

Intracardiac echocardiography (ICE) is widely used to facilitate transseptal puncture, assess the LA and pulmonary vein (PV) anatomy, as well as monitor accuracy of ablation lesions and complications.

However, ICE is an invasive tool, which requires additional venous puncture. Also, the cost of a single-use probe is not negligible.

Transoesophageal echocardiography (TEE) has been used for many years to assess LA anatomy, especially to exclude thrombus in the LA appendage (LAA), and also to facilitate transseptal puncture. TEE imaging is less invasive than ICE and use of TEE can lower costs as it can be used many times.

Alternatives to the large TEE probe may be the smaller S8-3t micro TEE probe and the S7-3t mini TEE probe. Both the micro TEE and mini TEE probes have been designed for pediatric use, but the intended use of the devices allows usage in adults depending on image quality needs.

- The micro TEE is smaller than the mini TEE and therefore even usable for neonates. The introduction of the micro TEE in the esophagus might be easier, based on the dimensions of the tip of the probe. However, micro TEE is expected to provide limited image quality and color Doppler flow capability in adults.
- Compared to the S8-3t micro TEE probe, the S7-3t mini TEE probe is expected to exhibit superior image and color Doppler imaging, also at deeper levels in adults, based on device specifications.

The aim of the present study is to evaluate the micro TEE and mini TEE for usability in terms of manipulability and image quality for transseptal puncture and to gain insight in the capabilities of micro and mini TEE to image selected LA anatomy that can possibly be used for additional information during AF ablation procedures. All TEE data will be compared with the routinely used ICE-catheter.

Doel van het onderzoek

micro TEE and mini TEE can view the same required anatomical features as ICE for atrial

transseptal puncture guidance.

Onderzoeksopzet

peri-procedural

Onderzoeksproduct en/of interventie

Transseptal puncture guidance by micro or miniTEE compared to ICE guidance.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Subjects who will be undergoing a left atrial ablation procedure where routinely ICE imaging is used
- Subjects who will be subject to a procedure where atrial transseptal puncture is required
- Subject who are 18 years of age or older

- Subject who are willing to give informed consent to participate in the study

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Patients unwilling or unable to give informed consent

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-08-2015
Aantal proefpersonen:	40
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	14-07-2015
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 43746

Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5160
NTR-old	NTR5300
CCMO	NL53139.044.15
OMON	NL-OMON43746

Resultaten