Usefulness of micro TEE and mini TEE imaging for EP procedures

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25982

Source
Nationaal Trial Register

Health condition

atrial fibrillation, ablation, EP procedures

Sponsors and support

Primary sponsor: Philips Healthcare, Best, the Netherlands
Source(s) of monetary or material Support: Philips Healthcare, Best, the Netherlands

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

•The scoring of the preference of the physician for the type of imaging at the moment of

transseptal puncture.

•The scoring of manipulability of micro or mini TEE probe by discretion of the physician.

•The scoring of intubation of micro or mini TEE probe in the esophagus of the patient by discretion of the physician.

•The fusion of anonymized X-ray fluoroscopy and micro TEE / mini TEE for database built-up to develop a fused X-ray/echography imaging device.

Study description

Background summary

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.

Study objective

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

Study design

peri-procedural

Intervention

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

Contacts

Public
MST Twente

Stevenhagen
Enschede
The Netherlands
Scientific
MST Twente

Stevenhagen
Enschede
The Netherlands

Eligibility criteria

Inclusion criteria

•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

Exclusion criteria

•Patients unwilling or unable to give informed consent

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-08-2015
Enrollment:	40
Type:	Anticipated

Ethics review

Positive opinion

Date:	14-07-2015
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 43746
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

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

Study results