

Usefulness of microTEE and miniTEE imaging for EP procedures

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The primary objective of this Clinical Investigation is to evaluate that micro and mini TEE can view the same required anatomical features as ICE for atrial transseptal puncture guidance.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac arrhythmias
Study type	Observational invasive

Summary

ID

NL-OMON43746

Source

ToetsingOnline

Brief title

micro and mini TEE study

Condition

- Cardiac arrhythmias

Synonym

atrial fibrillation

Research involving

Human

Sponsors and support

Primary sponsor: Philips

Source(s) of monetary or material Support: Philips

Intervention

Keyword: EP procedures, microTEE, miniTEE

Outcome measures

Primary outcome

The inclusion of 40 patients and the off line analysis of the comparison of micro and mini TEE imaging compared with regular ICE imaging. The off line analysis 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. The fusion of both images will allow the study team to develop a better image quality for use in interventional cardiac procedures.

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

The primary objective of this Clinical Investigation is to evaluate that micro and mini TEE can view the same required anatomical features as ICE for atrial transseptal puncture guidance.

Study design

This is a randomized controlled, unblinded, single center study.

Study burden and risks

A released ultrasound product (iE33 + S8-3t microTEE probe + S7-3t mini TEE probe) will be used within their intended use. A micro or mini TEE ultrasound examination is considered to be completely harmless and within the applicability of the safety report of the released iE33, S8-3t and S7-3t products.

Additional burden:

-The study will prolong the total procedure time, this will be approximately 10 minutes.

-The study will require additional X-ray images. The amount of X-ray radiation involved is negligible compared to the radiation of the total treatment.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

-Subjects who will be undergoing a left atrial ablation procedure where routinely ICE imaging is used

Exclusion criteria

-Subject younger than 18 years of age

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 04-01-2016

Enrollment: 40

Type: Actual

Medical products/devices used

Generic name: micro and mini transesophageal echocardiography

Registration: Yes - CE intended use

Ethics review

Approved WMO

Date: 01-09-2015

Application type: First submission

Review commission: METC Twente (Enschede)

Approved WMO

Date: 01-11-2016

Application type: Amendment

Review commission: METC Twente (Enschede)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 25982

Source: Nationaal Trial Register

Title:

In other registers

Register	ID
CCMO	NL53139.044.15
OMON	NL-OMON25982