Usefulness of Micro-TEE imaging for structural heart disease procedures

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

Summary

ID

NL-OMON40823

Source
ToetsingOnline

Brief title
Micro-TEE for SHD procedures

Condition

- Cardiac valve disorders

Synonym
structural heart disease, Valvular heart disease

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: Probe ter beschikking gesteld door Philips Healthcare. Oldelft is producent van deze probe.

Intervention

Keyword: Imaging, Micro TEE, Structural heart disease, Transesophageal echo

Outcome measures

Primary outcome

The primary objective of this clinical study is:

• to establish that microTEE can view the same required anatomical features as

TEE and ICE for their respective purposes.

Secondary outcome

The secondary objectives are:

• to establish that microTEE can be used without the use of general anesthesia

• to establish that transnasal use of a S8-3t microTEE probe is feasible

• to collect anonymised X-ray fluoroscopy and microTEE data for prototype

development of fused X-ray and echography imaging

Study description

Background summary

In recent years there has been a strong increase in the number of innovative percutaneous cardiac interventions for the treatment of patients with structural heart disease. These interventions allows the treatment of patients who previously were at too high risk for a surgical operation.
Echocardiography using TEE or ICE imaging are crucial for guiding these procedures. Recently, a microTEE probe for transesophageal imaging in children has become available.
This study is evaluating whether the microTEE can be used in place of the current TEE probe, or intra-cardiac ultrasound catheters (ICE) in adult with a structural heart disease.
The use of the microTEE probe may have the following advantages compared to the current TEE probe or ICE:
- The MicroTEE probe is much smaller than the current TEE probe which is less invasive and risks to patient are lower.

- Less invasive than intracardiac echo because venapuncture is no longer necessary
- Because the probe smaller / less invasive, it is expected that the probe is better tollerated and general anaesthesia might not be necessary anymore with less risks for the patient and cost-saving.
- The MicroTEE can be reused which is costsaving compared to the disposable catheters used in ICE.

Study objective

This study is aimed at evaluate whether the microTEE can be used in stead of the current TEE probe, or intracardiac ultrasound catheters (ICE) in adults with a structural heart disease.
The aim of the study is to compare image quality, the workflow and the ability to visualize the probe using the MicroTEE various cardiac structures and to compare it with the current standard (TEE or ICE). Anonimized images will be saved to use for a prototype software for the fusion of X-ray and ultrasound images.

Study design

Patients who are scheduled to undergo a procedure concerning structural heart disease will be contacted if prior to the procedure additional recordings with the MicroTEE probe can be made. After this procedure will be carried out with the guidance of TEE or ICE in the usual way

Intervention

Additional recordings with MicroTEE probe prior to the scheduled procedure which is currently guided by TEE or ICE will be made

Study burden and risks

Minimal burden and risk for the patient. Prior to the study only a few images with MicroTEE probe will be made before the initiation of the planned procedure which is currenlty guided by TEE or ICE imaging. Patients are in the majority of cases under general anesthesia so there is no burden in these patients. In patients who do not receive general anesthesia we will examine if the microTEE probe is well tolerated.

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 cardiac intervention where routinely TEE or ICE imaging is used
• Subjects who will be subject to a procedure where atrial transseptal puncture is required
• Subjects who will undergo a LAA (left atrial appendage) closure procedure
• Subjects who will undergo a PFO (patent fossa ovalis) closure procedure
• Subject who are 18 years of age or older
• Subject who will give informed consent to participate in the study

Exclusion criteria

• Subject is younger that 18 years of age
• Subjects who will not give informed consent to participate in the study

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-10-2014
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	MicroTEE probe
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	27-10-2014
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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: 22253
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL49744.100.14
OMON	NL-OMON22253