EchoNavigator 3D Models

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24577

Source
NTR

Health condition

Structural Heart Disease procedures: LAAC, TMVR and TAVI

Sponsors and support

Primary sponsor: Philips Medical Systems B.V.
Source(s) of monetary or material Support: Philips Medical Systems B.V.

Intervention

Outcome measures

Primary outcome

The primary endpoint is a qualitative and quantitative assessment by comparing the distances between
annotations genered automatically by the model with manual annotated structures and/or validating the
position of the annotations by contrast enhanced X-ray angio or the location of X-ray opaque structures (e.g.
devices) on the X-ray image.

Secondary outcome

Secondary endpoints are qualitative feedback on the user interfaceto improve
the investigational device, eecorded anonymized raw Echo and X-ray data to tune algorithm parameters and
qualitative to improve future versions of the EchoNavigator device.

Study description

Study objective

To determine the clinical value and impact of 3D TEE models for image guidance during SHD interventions in both a qualitative and quantitative approach:

• Qualitative: do the models help in understanding the relation between the cardiac structures from echo and the projected X-ray fluoroscopy image to support imaging and device guidance

• Quantitative: by a comparative measurement of structures provided by the 3D model and manual placed annotations

Study design

The patients will be participating in the trial for the duration of the procedure. No-follow-up is required per protocol.

Intervention

No interventions to the normal way of working in the protocol, study is observational.

Contacts

Public
Department of Cardiology - HerzKlinik Hirsianden

Roberto Corti
Witellikerstrasse 40

Zurich 8032
Switzerland
Scientific
Department of Cardiology - HerzKlinik Hirsianden

Roberto Corti
Witellikerstrasse 40

Zurich 8032
Switzerland

Eligibility criteria

Inclusion criteria

Patients that require one of the following SHD interventions for which routine fluoroscopy and TEE guidance is used: MitraClip placement on the mitral valve (TMVR), left atrial appendage closure (LAAC), trans catheter aortic valve implantation (TAVI)

• Subject is 18 years of age or older, or of legal age to give informed consent per state or national law

Exclusion criteria

-Patients who are unsuitable to accept TEE imaging during a SHD intervention, further descibed in the Clinical Research Plan.

-Subject participates in a potentially confounding drug or device trial during the course of the study.

-Subject meets an exclusion criteria according to national law (e.g. Age, pregnant woman, breast
feeding woman)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)

Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2016
Enrollment:	30
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5612
NTR-old	NTR5718
Other	Philips Medical Systems b.v. : DHF250438

Study results