Planning to Live and Easy Echo for Mitral Interventions

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON29681

Source
NTR

Health condition

Structural heart disease

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

The primary endpoint is clinical feedback on workflow, usability, and clinical impact of the device

Secondary outcome

Procedure time, radiation dose (DAP and AK), contrast agent used during interventions. Procedural parameters such as number of positioning attempts, complication rates, adverse events, adverse device effects, device deficiencies that could led to an SAE.

Study description

Background summary

This evaluation investigates the workflow improvements, usability, and potential clinical impact of new software solutions to be used in the planning of and/or during structural heart disease interventions. Qualitative feedback of the software usage will be collected in order to understand how well the software supports and improves the current percutaneous intervention. Also, patient demographics, procedure time, contrast usage and adverse events will be collected for comparison to historical data.

Study objective

This evaluation does not have a hypothesis to be tested since it is intended to evaluate the workflow and usability of the new software solution, without prior defined performance criteria.

Study design

The total duration of the study is expected to take approximately 24 months.

Intervention

The study will be conducted as per standard of care for the implantable devices indicated for patients.

The following procedure steps are additional to standard of care:

- Pre- and peri-interventional planning and verification using multimodality imaging

- Image-based guidance of catheters and devices on a separate display window
After the procedure is finished, the patient will leave the study.

Contacts

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Eligibility criteria

Inclusion criteria

• Subjects undergoing an SHD procedure and/or

• Subjects undergoing SHD procedural planning

• Subject is 18 years of age or older

• Subject is able to give informed consent, or of legal age to give informed consent per national law

Exclusion criteria

• Subject unable or unwilling to sign informed consent

• 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):	15-02-2018
Enrollment:	100
Type:	Anticipated

Ethics review

Positive opinion

Date:	15-02-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 44552
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6836
NTR-old	NTR7073
CCMO	NL63726.100.17
OMON	NL-OMON44552

Study results

Summary results
It is the intention of the investigator and sponsor to submit the clinical study data for publication.