The Contribution of EchoNavigator Workflow Improvements on Efficiency for SHD Procedures

No registrations found.

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

Summary

ID

NL-OMON26536

Source
Nationaal Trial Register

Health condition

Structural Heart Diseases (SHD)

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 of the study is a qualitative assessment of the usefulness, accuracy and contribution to efficiency of automated views as proposed by the Investigational Device. The qualitative assessment will be based on a relative scale (e.g. ranging from ‘very useful’ to ‘not useful’).

Secondary outcome

Qualitative feedback on the user interface and the workflow that may be used to improve the investigational device, clinical user feedback for potential future improvements of the device.

Study description

Background summary

The study investigates concept and feasibility of view automation for SHD interventions. The study will explore the contribution of semi-automatic views based procedural context, anatomy and device information on the ease of use and efficiency of the procedure.

Study objective

Semi-automatic views contribute to the ease of use and efficiency of the procedure.

Study design

The patients will be participating in the trial for the duration of the procedure. For the enrolled patients the qualitative assessment (relative scale) and feedback will be captured by an electronic case report form. First patient enrolment is in June 2021, last patient enrollment (N=200) before November 2022.

No-follow-up is required per protocol.

Intervention

No interventions to the normal way of working in the protocol, study is observational. Patients will receive standard of clinical care.

Contacts

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Eligibility criteria

Inclusion criteria

Subject is a patient that requires SHD intervention for which routine fluoroscopy and TEE guidance is used, such as: transcatheter mitral and tricuspid therapies (TTMT), left atrial appendage closure (LAAC), trans catheter aortic valve replacement (TAVR). Subject is able to give informed consent and is 18 years of age or older, or of legal age to give informed consent per state or national law.

Exclusion criteria

Subjects who are unsuitable to accept TEE imaging during a structural heart disease intervention
 Subject is an adult who lacks the capacity provide consent
 Subject is in an emergency condition
 Subject participates in a potentially confounding drug or device trial during the course of the study
 All vulnerable subjects, or any other subject who meets an exclusion criteria, according to applicable national laws, if any.
 Subject is pregnant or breast feeding woman
 Subject is Philips employee their family members residing with this Philips employee.

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):	01-06-2021
Enrollment:	200
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	11-05-2021
Application type:	First submission

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	NL9506
Other	Philips Medical Systems B.V. : DHF377257

Study results