

The Contribution of EchoNavigator Workflow Improvements on Efficiency for SHD Procedures

Gepubliceerd: 11-05-2021 Laatste bijgewerkt: 18-08-2022

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

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON26536

Bron

Nationaal Trial Register

Aandoening

Structural Heart Diseases (SHD)

Ondersteuning

Primaire sponsor: Philips Medical Systems B.V.

Overige ondersteuning: Philips Medical Systems B.V.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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').

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status: Werving nog niet gestart

(Verwachte) startdatum: 01-06-2021

Aantal proefpersonen: 200

Type: Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum: 11-05-2021

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register

NTR-new

Ander register

ID

NL9506

Philips Medical Systems B.V. : DHF377257

Resultaten