Planning to Live and Easy Echo for Mitral Interventions

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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.

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

Samenvatting

ID

NL-OMON29681

Bron
NTR

Aandoening

Structural heart disease

Ondersteuning

Primaire sponsor: Philips Medical Systems Nederland B.V.
Overige ondersteuning: Philips Medical Systems Nederland B.V.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• 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)

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	15-02-2018
Aantal proefpersonen:	100
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	15-02-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 44552
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6836

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

Resultaten

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