Concept and Feasibility Investigation of Planning to Live and Easy Echo for Mitral Interventions

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac valve disorders
Study type	Observational non invasive

Summary

ID

NL-OMON44552

Source
ToetsingOnline

Brief title
Planning to live for Mitral (P2L4M)

Condition

- Cardiac valve disorders

Synonym
structural heart disease, valve disease

Research involving
Human

Sponsors and support

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

Intervention

Keyword: fusion, imaging, mitral, planning

Outcome measures

Primary outcome

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

1) Define critical anatomical structures, markers, anatomical views, and measurements on CT and ultrasound required for mitral and other structural heart disease procedures

2) Define critical overlay annotations for clinically significant guidance

3) Generate hypotheses on measurable impact parameters of imaging

Secondary outcome

Secondary endpoints include:

- 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

Minimally invasive mitral valve interventions require complex CT planning and intra-procedural imaging. The research software application facilitates the processing and display of multimodal information to prepare and guide these new complex procedures.

The Philips supporting visualizations for heart interventions consist of two components:
1. Before the intervention, the Philips computer automatically finds the heart's structures in the CT scan. These heart structures are visualized together with automatic measurements. The attending cardiologist looks at the CT images together with the supporting visualizations to prepare the intervention.

2. During the intervention, CT, X-ray and echo images are cleverly combined into one single image. By bringing all the data together, there is a better image for the treating cardiologist.

Study objective

The purpose of Part 1 of the research is to look at the usability and accuracy of the automatically determined CT visualizations and measurements.

The purpose of Part 2 of the study is to determine whether the use of the combined information provides the cardiologist with additional information compared to the standard transesophageal echo and standard x-ray images separately. As a result, cardiac catheterisation may be easier.

The results of the study are used to optimize future commercial products.

Study design

This is a prospective, non-randomized, unblinded, observational, single-center study.

Study burden and risks

There are no possible risks or additional direct benefits associated with participation in this research compared with standard of care treatment.

Contacts

Public
Philips

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NL
Scientific
Philips

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NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

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

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-09-2018
Enrollment:	100
Type:	Actual

Medical products/devices used

Generic name:	Imaging software
Registration:	No

Ethics review

Approved WMO

Date:	17-04-2018
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 29681
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL63726.100.17
OMON	NL-OMON29681