Evaluation of workflow improvements of new software solution to be used during coronary interventions

No registrations found.

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

Summary

ID

NL-OMON25377

Source
Nationaal Trial Register

Health condition

Coronary Artery 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

Qualitative feedback of the use of the study device in order to establish an optimized workflow and usability.

Secondary outcome

Image data, adverse events, adverse device effects and device deficiencies that could have

led to a serious adverse event.

Study description

Background summary

This evaluation investigates the workflow improvements of new software solutions to be used during coronary interventions. Qualitative feedback of the software usage will be collected in order to understand how well the software supports and improves the current percutaneous coronary intervention workflow. Also, patient demographics, procedure time, contrast usage and adverse events will be collected for comparison to historic 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 9 months.

Intervention

The patient will undergo standard of care medical treatment for his or her cardiac condition. During the procedure, the physician may make angiograms for diagnosis and as reference for device navigation as part of the standard care. These angiograms will be automatically processed in the new software solution and displayed on fluoroscopy for navigation support. In case a balloon catheter is inserted into the coronary arteries, the physician may take cine images as part of the standard care. These images can be automatically enhanced in the new software solution. After the procedure is finished, the patient will leave the study.

Contacts

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Eligibility criteria

Inclusion criteria

-Subject will be undergoing a percutaneous coronary angiography or intervention

-Subject is 18 years of age or older, or of legal age to give informed consent per national law

Exclusion criteria

-Subject participates in a potentially confounding drug or device trial during the course of the study. Co-enrollment in concurrent trials may be allowed provided that pre-approval is obtained from Philips.

-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: Recruitment stopped

Start date (anticipated):	01-07-2015
Enrollment:	90
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion Date:	25-06-2015
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	NL5092
NTR-old	NTR5224
Other	Ethikkommission der Medizinischen Fakultät der Heinrich-Heine-Universität Düsseldorf, Kinderklinik : XCY607-130094

Study results