Evaluation of workflow improvements of new software solution to be used during coronary 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 gestopt
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON25377

Bron
Nationaal Trial Register

Aandoening

Coronary Artery 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

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

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 9 months.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

-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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

-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).

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 gestopt
(Verwachte) startdatum:	01-07-2015
Aantal proefpersonen:	90
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	25-06-2015
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	ID
NTR-new	NL5092
NTR-old	NTR5224
Ander register	Ethikkommission der Medizinischen Fakultät der Heinrich-Heine-Universität Düsseldorf, Kinderklinik : XCY607-130094

Resultaten