Xres5 beeldbewerking
Onderzoek met een nieuw röntgenbeeld bewerkingssysteem (Xres5)

Gepubliceerd: 18-09-2018 Laatst bijgewerkt: 15-05-2024

Xres5 image processing will allow for radiation dose or contrast concentration or radiation dose reduction while maintaining appropriate diagnostic image quality.

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

Samenvatting

ID

NL-OMON29354

Bron
NTR

Verkorte titel
Xres5

Aandoening

Coronary artery disease, X-ray, image quality

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 main study endpoints will be several dedicated and fine-tuned Xres5 EPXs which can be

used in combination with I) standard, II) reduced contrast medium concentration and III) reduced radiation dose, imaging conditions.

Toelichting onderzoek

Achtergrond van het onderzoek

The study will evaluate and optimize the performance of a new X-ray image processing algorithm for coronary procedures. The study will consist of a pilot phase during which the algorithm will be optimized and evaluated under a variety of imaging conditions. During the subsequent study phase the algorithm will not be changed anymore and image quality will be semi-quantitatively scored comparing images processed with the new algorithm to images with the current Clarity IQ algorithm. This will be done by both the interventional cardiologist performing the study procedure as by a blinded international review panel.

Doel van het onderzoek

Xres5 image processing will allow for radiation dose or contrast concentration or radiation dose reduction while maintaining appropriate diagnostic image quality.

Onderzoeksopzet

Only study procedures during the coronary procedure. No follow up.

Onderzoeksproduct en/of interventie

No interventions.

Contactpersonen

Publiek

Philips
Iris ter Horst

642549565

Wetenschappelijk

Philips
Iris ter Horst

642549565

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• Subject will be undergoing an elective coronary catheterization.
• For phase Ia, Ic, Id and 2/3: both patients undergoing diagnostic and interventional procedures can be included.
• For phases 1b, only patients undergoing PCI will be included.
• 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 with contrast allergies
• Subject with severe kidney disease (e-GFR<60* by Modification of Diet in Renal Disease (MDRD)/Cockcroft Gault clearance formula and/or upon decision by investigator)
• 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)
• Subject with overt hyperthyroidism

*for phase Id, patients with an e-GFR between 30 and 60 can also be included. In that stage of the study the Xres5 cine EPXs have already been fine-tuned. Indicating that the risk of, or the need for, an additional run, and thereby a potential increase in contrast medium exposure has been eliminated. Furthermore, as fluoroscopy is not meant for diagnosis it is rarely used in combination with contrast administration. Any dissatisfaction with Xres5 fluoroscopy IQ, requiring additional fluoroscopy with Clarity fluoroscopy, will not involve contrast medium administration. For phase 2/3, patients with an e-GFR30-60 can also be included if the physician chooses to use the reduced iodine Xres5 EPX. In that setting the patient could actually benefit from participation as the total contrast load would be reduced.

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 gestart
(Verwachte) startdatum:	08-10-2018
Aantal proefpersonen:	330
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	18-09-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 48824
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7273
NTR-old	NTR7488
CCMO	NL65015.028.18
OMON	NL-OMON48824

Resultaten