Xres5 beeldbewerking
Onderzoek met een nieuw röntgenbeeld bewerkingssysteem (Xres5)

No registrations found.

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

Summary

ID

NL-OMON29354

Source
NTR

Brief title
Xres5

Health condition

Coronary artery disease, X-ray, image quality

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

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.

Secondary outcome

Semi-quantification of diagnostic Image quality performance scored by a blinded international review panel (described below).

Study description

Background summary

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.

Study objective

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

Study design

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

Intervention

No interventions.

Contacts

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Eligibility criteria

Inclusion criteria

• 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.

Exclusion criteria

• 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.

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:	Recruiting
Start date (anticipated):	08-10-2018
Enrollment:	330
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	18-09-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 48824
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

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

Study results