Contrast Medium Reduction with AlluraClarity for Alliac/Peripheral and EVAR procedures

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

Samenvatting

ID

NL-OMON25607

Bron
Nationaal Trial Register

Aandoening

Endovascular Procedures
Abdominal Aneurysm

Ondersteuning

Primaire sponsor: Philips Medical Systems Nederland B.V.
Veenpluis 4-6
5684 PC Best
The Netherlands
Overige ondersteuning: Philips Medical Systems Nederland B.V.
Veenpluis 4-6
5684 PC Best
The Netherlands

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Compare the amount of contrast medium required to perform iliac/peripheral and EVAR procedures using the AlluraClarity control settings and the study settings, at similar procedure complexity quantified as fluoro time, number of DSA images and number of DSA runs.

Toelichting onderzoek

Achtergrond van het onderzoek

The AlluraClarity is developed by Philips Medical Systems, a Philips Healthcare company. The proposed AlluraClarity is a novel X-ray imaging technology, successor of the previous family of angiography systems, Allura Xper.

Contrast medium induced nephrotoxity is considered an important cause of hospital acquired renal failure. The goal of the study is to validate the hypothesis that it is possible, based on the relationship between image quality, patient dose and parameters affecting contrast medium, to find a compromise among them in order to reduce the administrered volume of contrast medium injected, at the expense of patient radiation dose, while maintaining clinically acceptable image quality.

Principal Investigator: Michiel de Haan, Maastricht University Medical Center

Doel van het onderzoek

The goal of the study is to validate the hypothesis that it is possible, based on the relationship between image quality, patient dose and parameters affecting contrast medium, to find a compromise among them in order to reduce the administrered volume of contrast medium injected, at the expense of patient radiation dose, while maintaining clinically acceptable image quality.

Onderzoeksopzet

Subjects are enrolled in the study for the duration of the interventional procedure. No follow-up is required. Patients will be followed according to regular clinical standard of care.

The total duration of the study is expected to take approximately 2 years.

Onderzoeksproduct en/of interventie

The study is divided in 3 phases:

Phase 0: Radiation dose reduction and determination of the optimum reduced dose level. (20 patients for iliac and 20 for EVAR procedures, 40 in total)

Phase 1: Double injection per patient: once with the optimum settings found in phase 0, and the second time with a reduced amount of contrast agent and gradual increase of the radiation dose. The optimum combination of reduced contrast agent and increased radiation will be determined. (20 patients for iliac and 20 for EVAR procedures, 40 in total)

Phase 2: A prospective randomized observational un-blinded single center study using the two optimum settings determined in phases 0 and 1. (90 patients for iliac and 90 for EVAR, 180 in total)

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen

(Inclusiecriteria)

-Subject will be undergoing an EVAR or iliac/peripheral procedure

-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 <45 by Modification of Diet in Renal Disease (MDRD formula)

-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

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 nog niet gestart
(Verwachte) startdatum:	01-06-2017
Aantal proefpersonen:	260

Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	14-04-2017
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	NL6165
NTR-old	NTR6312
Ander register	Philips protocol (study plan) nummer : XCY607-130043

Resultaten