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

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Primary objective:- to 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...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Arteriosclerosis, stenosis, vascular insufficiency and necrosis
Study type	Interventional

Summary

ID

NL-OMON47473

Source
ToetsingOnline

Brief title
Contrast Medium Reduction with AlluraClarity (COMER)

Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
Endovascular aneurysm repair and iliac/peripheral procedure

Research involving
Human

Sponsors and support

Primary sponsor: Philips
Source(s) of monetary or material Support: Philips Healthcare

Intervention

Keyword: AlluraClarity, Contrast Medium

Outcome measures

Primary outcome

The following endpoints will be measured in Phase 2:

- The amount of contrast used for each subject will be measured as contrast medium volume, flow, concentration, iodine delivery rate, iodine load.

- Procedure complexity is quantified as fluoroscopy time, number of DSA runs and number of DSA images

- Physician switch-backs will be quantified by the amount of DSA runs performed with control settings during a procedure which is supposed to be performed with study settings in phase 2.

- Patient radiation dose will be quantified as DAP fluoro, DAP exposure, total DAP, and Air Kerma

Secondary outcome

not applicable

Study description

Background summary

The AlluraClarity system has been developed by Philips Healthcare. The AlluraClarity is a novel X-ray imaging technology, successor of the previous family of angiography systems, Allura Xper. Radiation dose reduction using AlluraClarity technology has already been investigated in many clinical domains by comparing it to the state-of-the-art reference Allura Xper. In iliac procedures, patient radiation dose reduction of 83% during DSA has been reported, with procedural patient radiation dose reduction of 57% for EVAR and 73% for iliac, at similar procedure complexity. Diagnostic and interventional

procedures use contrast media. Contrast medium induced nephropathy 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 radiation dose and parameters affecting contrast medium, to find a compromise among them in order to reduce the administered volume of contrast medium injected, at the expense of patient radiation dose, while maintaining clinically acceptable image quality.

Study objective

Primary objective:
- to 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

Secondary objectives:
- to demonstrate that study settings and diluted contrast medium injection protocols for DSA can be used for an entire procedure (i.e. prove that the physician never switches back during the procedure to control settings and the standard contrast medium injection protocol)
- to evaluate the change in radiation dose required to minimize contrast medium usage for the new proposed study settings

Study design

The study is divided in three phases:

Phase 0 is a prospective un-blinded cohort study. The current AlluraClarity acquisition settings will be further tuned to investigate whether a further reduction in patient radiation dose can be achieved. Tuning of the acquisition settings will be done by an IQ specialist together with the interventional radiologist. The tuning is a regular Philips process. Images will be grabbed via an image grabber which is property of Philips. These images are grabbed at the detector and contain raw images (de-identified). The new acquisition system settings (referred to as *control settings*) will be used with standard injection protocol (referred to as *SIP injection*).
Phase 0 is needed to define the starting point of the study and reduce the radiation dose if possible. It is possible that lower dose than currently used in the lab is not possible. In that case, Phase 0 will be immediately terminated.

Phase 1 is a prospective un-blinded cohort study. Starting with the control settings as defined in Phase 0 and SIP, the AlluraClarity will be tuned to achieve contrast medium reduction at the expense of patient radiation dose. Tuning of the acquisition settings will be done by an IQ specialist together

with the interventional radiologist. In this phase, on the same AlluraClarity system, control and study settings will be made available
Phase 1 will be evaluated using a double DSA injection on the same patient. Injection 1 will be acquired with control settings and standard injection protocol, injection 2 will be acquired with study settings and diluted injection protocol. The expectation is to dilute contrast medium in small steps, combined with a dose increase for every new tuning step. The increase in patient entrance dose will never exceed the boundary of the previous family of X-ray systems, Allura Xper. It has been reported in peer reviewed journals that AlluraClarity reduces the patient radiation dose with 83% in DSA for peripheral procedures, with procedural patient radiation dose reduction of 57% for EVAR and 73% for iliac, at similar procedure complexity. To avoid learning bias, the order of injection 1 and 2 will be performed based on a randomization table. The randomization table will be generated before start of the trial from a web based application such as Research Randomizer (https://www.randomizer.org/) or similar, and stored in the investigational brochures so that it is easily accessible by the staff before a procedure starts to define the allocation of the subject to the right treatment arm.
During this phase, the field of view will be appropriately collimated, as per standard of care. The projection angle will be selected from most commonly and universally used projections in clinical practice, allowing assessment of both small and large vessels. The injections will be made with a one-minute pause to ensure clearance of contrast agent from the vasculature and without modifying the table position, C-arc position, detector format, detector position, collimator, wedge position, or catheter position. In this way, only the acquisition settings and injection protocol will be the variables. The images will be grabbed via an image grabber which is property of Philips. These images are grabbed at the detector and contain raw images (de-identified). As part of the tuning phase, the physician will assess the images side-by-side to make sure that there is no loss of information due to lower contrast medium injection.

Phase 2 is a prospective un-blinded randomized controlled group trial with two treatment groups (i.e., study group with study settings and diluted contrast medium injection protocol as defined in Phase 1 and the control group with control settings as defined in Phase 0 and standard injection protocol). The randomization table will be generated before the start of the trial from a web based application such as Research Randomizer (https://www.randomizer.org/) or similar, and stored in the investigational brochures so that it is easily accessible by the staff before a procedure starts to define the allocation of the subject to the right treatment arm. The interventional radiologist will remain un-blinded as the physician cannot be blind to the acquisition settings for phase 2 as a different injection protocol has to be used based on the selected settings. However, the physician will be blind to the selection process as a different department is responsible of the patient planning in the labs. The aim is to compare the two groups in terms of procedural contrast medium used and procedural patient dose in relation to procedural complexity

(quantified by fluoroscopy time, number of DSA images and number of DSA runs). In addition, the acquisition settings used by the physician during the DSA acquisitions will be tracked to assess whether the physician ever switches back to control settings when patients should be treated with new acquisition settings (according to the randomization table). The reasons for switching back will also be tracked in the e-CRF. Also in this phase, the images will be grabbed via an image grabber which is property of Philips. These images are grabbed at the detector and contain raw images (de-identified).

Intervention

not applicable

Study burden and risks

In Phase 1 patients will be evaluated using a double DSA injection. Injection 1 will be acquired with control settings and standard injection protocol; Injection 2 will be acquired with study settings and diluted injection protocol. The expectation is to dilute contrast medium in small steps combined with a dose increase for every new tuning step. The increase in patient entrance dose will never exceed the boundary of the previous family of -ray systems, Allura Xper.
The results of the study will provide new acquisition settings that can be used with diluted injection protocol. This will benefit patients that have currently no possibility of being treated because at risk of contrast induced nephropathy to have access to the angiolab.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* Subject will be undergoing an EVAR or iliac/peripheral procedure
* Subject is 18 years of age or older

Exclusion criteria

* Subject with contrast allergies
* Subject with severe kidney disease (e-GFR<45, determined by the 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

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-03-2018
Enrollment:	260
Type:	Actual

Ethics review

Approved WMO

Date:	15-03-2017
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
CCMO	NL58143.068.16