Clinical validation and evaluation of X-ray image processing for endovascular Digital Subtraction Angiography and Intervention

Published: 27-04-2012
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The objective of the study is to assess image quality and diagnostic information in iliac angiography with a lower exposure dose.

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

Summary

ID

NL-OMON37509

Source
ToetsingOnline

Brief title
X-ray dose reduction study for interventional radiology

Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
vascular atherosclerosis, vessel narrowing

Research involving
Human

Sponsors and support

Primary sponsor: Philips
Source(s) of monetary or material Support: Philips Medical Systems Nederland B.V.

Intervention

Keyword: Image quality, Interventional radiology, X-ray dose reduction

Outcome measures

Primary outcome

Simultaneous visual comparison of image quality in the two groups, by blinded reviewers. Image quality is assesed by following a specific test protocol regarding vessel visibility.

Secondary outcome

N/A

Study description

Background summary

The increasingly complex nature of many endovascular interventions requires the use of significant amounts of radiation for their completion. However, procedures performed under fluoroscopy lead to an increased risk of radiation damage to tissues. Unnecessary exposure to any form of ionizing radiation should therefore be avoided. The reduction of radiation exposure is of particular importance in the pelvic area, since the reproductive organs of patients are either in the primary beam or in close proximity to it. This means that the radiation risk to the patient and future generations is much higher compared to examinations in which the gonads are farther from the primary beam. Hence, radiation dose during pelvic X-ray examinations needs to be investigated in order to reduce the radiation exposure. Any meaningful investigation of possible dose reductions must be conducted in conjunction with image quality measurements.

Study objective

The objective of the study is to assess image quality and diagnostic information in iliac angiography with a lower exposure dose.

Study design

Study design: patient-controlled

Masking: randomized, blinded review
Primary Purpose: Diagnostic

Study burden and risks

When exposed to high intensities, or for a long time. X-rays can be harmful. Contrast agent can damage kidneys when used in large quantities.The burden to the patient consists of an additional contrast injection under X-ray guidance. This will prolonge the total procedure with 1,5 minute. The radiation exposure during the additional contrast injection will be limited, as a low-dose protocol will be used. Additional radiation exposure to the patient will only occur if the image quality of the low-dose protocol proves insufficient, and the procedure thus needs to be finished with the standard dose. If the additional series with the low dose protocol proves to be of suffiecient quality, the procedure will be completed with that low dose settings. The total radiation dose during the procedure will then be significantly lower than with the standard treatment.

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

Patients older than 18 years of age undergoing iliac artery angiography

Exclusion criteria

- Patients not willing or unable to give consent to participate
- Patients already involved in a clinical trial
- Patients under the age of 18
- Pregnant or breastfeeding women
- Patients with kidney disease (eGFR < 60)

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-07-2012
Enrollment:	40
Type:	Actual

Medical products/devices used

Generic name:	X-ray system

Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	27-04-2012
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	03-06-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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
Other	het registratieproces is ingezet; het identificatienummer zal worden overlegd zodra deze bekend is en voordat de eerste patient zal worden geincludeerd
CCMO	NL39423.100.12