Reducing the amount of contrast medium in CTAs of the abdominal aorta using a multiphasic injection technique

Published: 06-09-2011 Last updated: 28-04-2024

Primary Objective: Is it possible to reduce the amount of contrast medium used in CTAs of the abdominal aorta by injecting the contrast medium with a multiphasic protocol, without losing image quality?Secondary Objective: What does the contrast...

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

Summary

ID

NL-OMON35498

Source ToetsingOnline

Brief title Multiphasic injection technique for CTAs

Condition

• Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym Bloodvessel deviations

Research involving Human

Sponsors and support

Primary sponsor: Jeroen Bosch Ziekenhuis

Source(s) of monetary or material Support: Voor dit onderzoek is geen extra geld nodig. Het zijn onderzoeken die toch al zouden plaatsvinden.

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Intervention

Keyword: Contrast medium, CTA, Injection technique, Multiphasic

Outcome measures

Primary outcome

- The amount of HU measured in the aorta at 30 positions from the celiac trunk

to the iliac arteries in both groups.

Secondary outcome

- The contrast enhancement curve over time in the aorta in the multiphasic

protocol.

- The uniformity of the attenuation values of both protocols.

- The volume of contrast medium that is used.
- The clinical usefulness of the scans determined by 3 blinded radiologists (of

whom one is not connected to the Jeroen Bosch Ziekenhuis) and scored at a scale

from 1 to 3.

Study description

Background summary

The amount of contrast medium delivered to a patient is of utmost concern due to the risks of complications, particularly contras-induced nephropathy (CIN). CIN is the third most common cause of hospital-acquired acute renal failure. CIN leads to prolonged hospitalization and higher medical costs. Therefore, ways to reduce the amount of contrast media are highly anticipated.

In literature the multiphasic injection method is described, in which the rate of injection exponentially decays, opposed to the current uniphasic technique that injects with a constant rate. Multiphasic injection is found to achieve better uniform prolonged enhancement, which is desirable, and can yield the same quality scans with a smaller amount of contrast medium. Patients undergoing an angiographic CT (CTA) scan of the abdominal aorta at the Jeroen Bosch hospital, receive 100 ml of 350 mg/ml iodine containing contrast material. Using the multiphasic injection technique we will reduce this amount to 89 ml.

Study objective

Primary Objective: Is it possible to reduce the amount of contrast medium used in CTAs of the abdominal aorta by injecting the contrast medium with a multiphasic protocol, without losing image quality? Secondary Objective: What does the contrast enhancement curve over time looks like using the multiphasic injection technique? With which protocol a more uniform contrast enhancement is reached?

Study design

Intervention study, feasibility study

Intervention

30 Patients are randomly assigned to either standard or multiphasic protocol. 15 Patients undergo standard protocol, 15 patients undergo the multiphasic protocol. The multiphasic protocol injects contrast medium with an exponential decay; the total volume of contrast medium is injected is less (89 ml instead of 100 ml). For research purposes low-dose scans will be made for an additional 20 seconds after the diagnostic scan is finished, at the position where the diagnostic scan stopped.

Study burden and risks

There is a risk that the scans of patients undergoing the multiphasic protocol will be of less quality, since less contrast medium is used. Worst-case scenario is that the patient will have to undergo another scan. Immediately after scanning the patients, the scans will be looked at by a radiologist to see if the image quality is sufficient. So when image quality is not sufficient, patients will be scanned again immediately and an additional needle prick is not necessary. The patients undergoing the multiphasic protocol will be subjected to a small additional amount of radiation, approximately 1 mSv, because of the low-dose scans that will be made after finishing the diagnostic scan.

Contacts

Public

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Referred for CTA of the abdominal aorta according to clinical indications
- Signed informed consent
- > 18 years
- Mentally competent
- Kidney function > 60 GFR

Exclusion criteria

- Kidney function < 60 GFR
- Allergy contrast medium
- Known arrhythmias or other heart disorders
- <18 years
- Pregnancy or lactation
- Mentally incompetent

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)

Primary purpose: Diagnostic

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	19-10-2011
Enrollment:	30
Туре:	Actual

Ethics review

Approved WMO	
Date:	06-09-2011
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

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

ССМО

ID NL37432.028.11