

Reducing the amount of contrast medium in CTAs of the abdominal aorta using a multiphasic injection technique and a test bolus to reduce the bolus volume

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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 an exponential decay and with a bolus reduction, without losing image quality?Secondary Objectives:...

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

Summary

ID

NL-OMON35570

Source

ToetsingOnline

Brief title

Multiphasic injection technique and bolus reduction 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.

Intervention

Keyword: Bolus reduction, Contrast medium, CTA, Multiphasic injection

Outcome measures

Primary outcome

The amount of Hounsfield Units (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 multiphasic injection with bolus reduction 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 radiologists 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 contrast-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. Ways to reduce the amount of contrast media are therefore highly anticipated.

In literature a multiphasic injection method is described. Here, the rate of

injection exponentially decays, opposed to the current uniphasic technique, which 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.

This uniform prolonged enhancement can be shortened with reducing the bolus volume by using the information extracted from the test bolus injection acquired prior to the multiphasic injection. Patients undergoing an angiographic CT (CTA) scan of the abdominal aorta at the Jeroen Bosch Ziekenhuis, receive 100 ml of 350 mg/ml iodine containing contrast medium. With the multiphasic injection technique and bolus reduction, we will reduce this amount to 50 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 an exponential decay and with a bolus reduction, without losing image quality?

Secondary Objectives:

What does the contrast enhancement curve over time look like using the multiphasic injection technique with a bolus reduction?

With which protocol a more uniform contrast enhancement is reached?

Study design

Intervention study, feasibility study

Intervention

Randomly, 15 Patients are assigned to undergo standard protocol, and 15 patients are assigned to undergo the multiphasic with bolus reduction protocol. The multiphasic protocol injects contrast medium with an exponential decay. The total volume of contrast medium injected is less, 50 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 with bolus reduction protocol will be of less quality, since less contrast medium is used. Worst case scenario is that the patient will have to undergo a second 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 with bolus reduction 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

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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
- Mentally competent
- Signed informed consent
- * 18 years

- Kidney function > 60 GFR

Exclusion criteria

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

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:	Recruitment stopped
Start date (anticipated):	01-12-2011
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO	
Date:	11-01-2012
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	ID
CCMO	NL38316.028.11