A non-invasive Cardiac Output measurement as a replacement of the test bolus technique during CT

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Primary Objective : What is the correlation between the CO and the delay in time between injecting the contrast medium and arrival of the contrast in the abdominal aorta Secondary Objective : Would it be possible to reduce the amount of contrast...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON37655

Source
ToetsingOnline

Brief title
Non-invasive cardiac output measurement replacing the test-bolus technique

Condition

- Other condition

Synonym
n.v.t.

Health condition

Alle patienten die komen voor CT abdomen.

Research involving
Human

Sponsors and support

Primary sponsor: Jeroen Bosch Ziekenhuis
Source(s) of monetary or material Support: Er zijn geen specifieke kosten verbonden. Aanschaf /lease Nexfin monitor door Cluster Beeldvormende Technieken JBZ is geregeld via clustermanager H.Geraerdts.

Intervention

Keyword: Cardiac Output, CT abdomen, CTA, Test Bolus Technique

Outcome measures

Primary outcome

- The cardiac output, measured by the Nexfin Monitor.

- The time delay, starting when the contrast medium is injected until the time

that de necessary amount of Hounsfield Units is reached.

Secondary outcome

- The correlation coefficient between the cardiac output and the delay time.

Study description

Background summary

In this investigation will be observed whether the testbolus technique can be replaced by a cardiac output measurement. This might be possible, if the correlation between the cardiac output and the delay can be described.
Both investigations are meant to reduce the total amount of contrast medium that's being used. This is a very important goal, as the use of contrast media could cause CIN (contrast induced nephropathy). Another advantage in the future will be that the low dose scans in testbolus/bolustriggering technique won't be necessary anymore for dertermination of delay time. This saves a small amount of radiation.

Study objective

Primary Objective : What is the correlation between the CO and the delay in time between injecting the contrast medium and arrival of the contrast in the abdominal aorta

Secondary Objective : Would it be possible to reduce the amount of contrast medium used in CT of the abdomen by using CO measurements as a replacement for test bolus technique?

Study design

This is a correlation study.

Study burden and risks

The patient will be subjected to a small amount of radiation, approximately 0,4 mSV, because of the low dose scans that will be made for measuring time delay. The additional amount of radiation is relatively small compared to the whole scan. The radiation on the whole scan is 10 mSv, depending on the size of the scan area. This is the amount of radiation that the patient always will receive for medical indication.

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
16,9 * BMI * 30,1

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):	10-03-2012
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	07-03-2012
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	NL39634.028.12