Effect of iodine concentration on Vascular Attenuation in CT Coronary Angiography

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· Explore the relative impacts of iodine concentration versus iodine delivery rate on intra-coronary attenuation. · Describe the effect of iodine concentration on contrast bolus characteristics e.g. bolus homogeneity, time-to-peak, and pressure...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Coronary artery disorders
Study type	Observational invasive

Summary

ID

NL-OMON37283

Source
ToetsingOnline

Brief title
CT-CON

Condition

- Coronary artery disorders

Synonym
coronary atherosclerosis coronary

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W,Bayer

Intervention

Keyword: Atherosclerosis, CT coronary Angiography, Iodine concentration

Outcome measures

Primary outcome

Assessment of coronary attenuation on a per-segment basis

Secondary outcome

na

Study description

Background summary

Contrast protocols in CT coronary angiography are designed to achieve a high intra-coronary attenuation because it improves both image quality and confidence of the reader. Moreover, it has been shown that higher intra-coronary attenuation improves the overall diagnostic accuracy of CT coronary angiography in the detection or exclusion of significant coronary stenoses[1]. Newly designed contrast media with higher iodine concentrations have been introduced in past years. It has been advocated to use these high-end contrast media in CT coronary angiography. However, it is currently unknown whether the use of high iodine concentration contrast media is beneficial as compared to low iodine concentrations if the iodine delivery rates (mgI/s) are the same.
We hypothesize that the use of contrast media with different iodine concentrations, but identical iodine delivery rates, results in a similar intra-vascular attenuation in CT coronary angiography.

Study objective

· Explore the relative impacts of iodine concentration versus iodine delivery rate on intra-coronary attenuation.
· Describe the effect of iodine concentration on contrast bolus characteristics e.g. bolus homogeneity, time-to-peak, and pressure curves during contrast media injection.

Study design

Observer-blinded, controlled, randomized trial. All subjects will undergo

clinically mandated CT coronary angiography using one of 4 standardly used scan protocols: Contrast media with different iodine concentrations will be delivered at a normalized iodine delivery rate (2.0 mgI/s).

Study burden and risks

All the protocols normally yield results sufficient for clinical use, and none of the protocols is associated with a heightened risk of adverse effects. Participation in this study will not cause any delay in the CT coronary angiography procedure. Thus, other than the randomization, the subject should not undergo any burden or risk from participation in this study.

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

Age > 30 years

Exclusion criteria

Contraindications for CT coronary angiography, including:
- Inability to perform a breath hold for at least the expected scan time
- Persistent arrhythmias (e.g. atrial fibrillation)
- Known allergy to iodinated contrast media
- Impaired renal function (serum creatinine >120 µmol/l)
- Possible pregnancy
- Unstable clinical condition (angina at rest, hypotension, malignant arrhythmias)
- Body weight exceeding 120 kg
· Inability to position an 18 G cannula in an antecubital vein
· Unable to give informed consent or no informed consent obtained

Study design

Design

Study type: Observational invasive

Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-07-2010
Enrollment:	700
Type:	Actual

Ethics review

Approved WMO

Date:	23-07-2009
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	06-07-2011
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL27074.078.09