# EFFECT OF ISO-OSMOLAR CONTRAST MEDIUM ON CORONARY OPACIFICATION AND HEART RHYTHM IN CORONARY CT ANGIOGRAPHY (ISO-COR)

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Demonstrate that with contemporary cardiac CT scan protocols good opacification of the coronary arteries can be achieved, that is similar to low-osmolar contrast media injected at the same iodine delivery rate. In addition, we will investigate the...

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

# Summary

### ID

NL-OMON40326

**Source** ToetsingOnline

Brief title ISOCOR

# Condition

• Coronary artery disorders

Synonym coronary atherosclerosis

**Research involving** Human

### **Sponsors and support**

**Primary sponsor:** Erasmus MC, Universitair Medisch Centrum Rotterdam 1 - EFFECT OF ISO-OSMOLAR CONTRAST MEDIUM ON CORONARY OPACIFICATION AND HEART RHYTHM ... 25-05-2025

#### Source(s) of monetary or material Support: GE Healthcare

#### Intervention

Keyword: atherosclerotic disease, CT coronary Angiography, Iso-osmolar contrast media

#### **Outcome measures**

#### **Primary outcome**

Demonstrate comparable coronary opacification by iodixanol 270 (iso-osmolar

contrast medium) in comparison to iopromide 300 (low-osmolar contrast medium),

when injected with a comparable iodine flux.

#### Secondary outcome

Investigate additional differences between iodixanol and iopromide, in terms

of:

- Effect on heart rate, heart rate variability and arrhythmia
- Venous contrast congestion (accumulation)
- Qualitative and quantitative image quality
- Patient discomfort and adverse events during and after injection

# **Study description**

#### **Background summary**

Non-invasive imaging of the coronary arteries to identify atherosclerotic disease and narrowing has over the past decade gained widespread acceptance in the diagnostic workup of suspected CAD [Montalescot 2013]. Different contrast media are available to opacify the coronary lumen. The contrast media vary in terms of iodine concentration and osmolality. Until recently the goal in coronary CT was to achieve high opacification to compensate for other limitations of CT, favouring high-concentration contrast media or high injection rates with lower concentrations.

However, cardiac CT has continued to evolve. Apart from improving image 2 - EFFECT OF ISO-OSMOLAR CONTRAST MEDIUM ON CORONARY OPACIFICATION AND HEART RHYTHM ... 25-05-2025 quality, much attention has been paid to the reduction of radiation exposure. Contemporary cardiac CT involves axial scan modes (as opposed to spiral modes), very short scan times, lower tube potentials, iterative reconstruction algorithms. These innovation warrant a critical look at what we expect or demand from our contrast media. The contrast medium and protocol we use should support our aim for high diagnostic quality, while minimizing the overall amount of contrast medium.

#### **Study objective**

Demonstrate that with contemporary cardiac CT scan protocols good opacification of the coronary arteries can be achieved, that is similar to low-osmolar contrast media injected at the same iodine delivery rate. In addition, we will investigate the effect of iso-osmolar contrast media on heart rate and variability in relation to image quality.

#### Study design

Double-blinded, randomized diagnostic validation trial

#### Study burden and risks

Both contrast media are approved and have been clinically used worldwide for many years. There are no additional risk for the participating patient.

# Contacts

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# **Trial sites**

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### **Listed location countries**

Netherlands

# **Eligibility criteria**

#### Age

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

#### **Inclusion criteria**

Age >18 yrs • Body weight 50 - 125 kg

### **Exclusion criteria**

- Pregnancy
- Renal dysfunction defined as eGFR<45 ml/min
- Allergies to iodine contrast media, manifest thyreotoxicosis
- Arrhythmia, including atrial fibrillation/flutter, 2nd or 3rd degree AV block, frequent ectopic beats prior to the exam (discretion of the referrer).
- Prior coronary artery bypass graft surgery or coronary stents
- Contraindications to the contrast media according to SPC (summary of product characteristics)

# Study design

### Design

Study type:	Observational invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Diagnostic

### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	15-10-2014
Enrollment:	300
Туре:	Anticipated

### Medical products/devices used

Product type:	Medicine
Brand name:	ultravist
Generic name:	iopromide 300
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Visipaque 270
Generic name:	lopdixanol 270
Registration:	Yes - NL intended use

# **Ethics review**

Approved WMO	
Date:	08-10-2014
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO	
Date:	25-02-2015
Application type:	First submission
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
EudraCT	EUCTR2014-000681-22-NL
ССМО	NL46493.078.14