# Diagnostic performance of MSCT in cardiomyopathy patients

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To evaluate the diagnostic effectiveness of MSCT in making a distinction between ischemic and non-ischemic cardiomyopathy in symptomatic patients. If MSCT proves to be a reliable diagnostic, ICA can be reserved for therapeutic purposes only. This...

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

## Summary

### ID

NL-OMON30959

**Source**
ToetsingOnline

**Brief title**
MSCT in cardiomyopathy patients

### Condition

- Coronary artery disorders

**Synonym**
coronary atherosclerosis

**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

## Intervention

**Keyword:** Cardiomyopathy, Coronary disease, Etiology, Spiral Computed, Tomography

## Outcome measures

### Primary outcome

Diagnostic performance of MSCT will be demonstrated in terms of specificity, sensitivity, PPV, NPV and accuracy. ICA will be used as the standard of reference. For the MSCT a combination of calcium scoring (first) and coronary angiography (second) will be performed.

### Secondary outcome

NA

# Study description

### Background summary

Cardiomyopathy
In 2006, the American Heart Association (AHA) published a scientific statement that proposed a contemporary definition and classification of the cardiomyopathies (CM);
"Cardiomyopathies are a heterogeneous group of diseases of the myocardium associated with mechanical and/or electrical dysfunction that usually (but not invariably) exhibit inappropriate ventricular hypertrophy or dilatation and are due to a variety of causes that frequently are genetic. Cardiomyopathies either are confined to the heart or are part of generalized systemic disorders, often leading to cardiovascular death or progressive heart failure-related disability1. Disease confined to the heart is called primary whereas generalized disease is called secondary.

The 2006 AHA scientific statement makes a distinction between cardiomyopathy and cardiac dysfunction due to known entities such as hypertension, valvular disease, congenital heart disease and also ischemic heart disease. This means that the term *ischemic cardiomyopathy* in theory is false1-2. In clinical practice however the term cardiomyopathy is also used for cardiac dysfunction of known cause. Here, the term cardiomyopathy will also be used for disease

caused by coronary atherosclerosis or other known causes.

**Study objective**

To evaluate the diagnostic effectiveness of MSCT in making a distinction between ischemic and non-ischemic cardiomyopathy in symptomatic patients. If MSCT proves to be a reliable diagnostic, ICA can be reserved for therapeutic purposes only. This will safe money and complications as previously discussed. Using the calcium score as a *rule out test* of disease, radiation exposure can be minimal especially in this patient group because around 30-50% of the cardiomyopathy patients is expected to be diagnosed as having non ischemic disease17. After a positive calcium score, both MSCT-CA and invasive angiography (ICA) will be performed and results (diagnoses) will be compared.

**Study design**

Prospective, diagnostic study. The primary endpoint will be the correct diagnosis by MSCT of ischemic versus non-ischemic cardiomyopathy. All patients that: visit a cardiologist of the Erasmus MC for specified complaints (see *patient population/ base*), fulfill the inclusion criteria, have no reason for exclusion and are willing to participate, will be included in the study in a chronological order. Patients that already visited a cardiologist at the Erasmus MC for specified complaints and are waiting for ICA, will also be asked to participate.

All patients will have ICA after MSCT-CA. MSCT-CA results will not be told to the patient before ICA. Whether the patient undergoes ICA or not depends on the MSCT-calcium scan results as previously mentioned. Results in grey boxes will be calculated, examined and compared

**Study burden and risks**

Participating in this study implies very little risk. There is a small risk of hematoma at the location of the i.v. cannula. If the patient has a positive calciumscore, contrast agents will be used during the remainder of the scan procedure. There is a small chance of minor nausea or skin rash. Only very seldom contrast agents provoke temporary renal failure and shock. All equipment needed for these (emergency) situations is available in the CT room. Further it is important to note that the risk of any complication is minimized by evaluating the patient risk profile before scanning. If there are any risk factors the scan will not be done.

# 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

- patient is symptomatic
- LVEF <45% and/ or FS<25% as measured by echocardiography.
- and/ or dilation on echo of left ventricle (male >60 mm./ female >55 mm.).
- cardiomyopathy of unknown origin (ischemic/non-ischemic).
- willing to participate.
- signed a written consent form approved by the ethical committee of Erasmus MC.
- MSCT possible within two months before invasive angiography.

## Exclusion criteria

- intolerance for Iodine.

- creatinine level >120.
- coronary stent placement or bypass grafting in the past.
- known myocardial infarction
- pregnancy
- not being able to breath hold for 15 seconds.
- under the age of twenty
- being incapacitated
- acute patients

# Study design

## Design

**Study type:** Observational invasive

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| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Diagnostic |

## Recruitment

NL

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|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 10-10-2007 |
| Enrollment: | 60 |
| Type: | Actual |

# Ethics review

Approved WMO

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| Date: | 21-09-2007 |
| 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 |
| --- | --- |
| CCMO | NL17627.078.07 |