

Non-invasive assessment of coronary artery disease in patients with chest pain

Submission date 26/02/2007	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 26/02/2007	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 26/03/2021	Condition category Circulatory System	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
NL446 (NTR486)

Study information

Scientific Title
Non-invasive assessment of coronary artery disease in patients with chest pain

Study objectives

In patients presenting with chest pain complaints and an intermediate risk of Coronary Artery Disease (CAD), Multi-Slice Computed Tomography (MSCT) will have a higher specificity as compared to Myocardial Perfusion Imaging (MPI). Accordingly, MSCT may serve as an accurate first-line evaluation tool.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the local medical ethics committee

Primary study design

Interventional

Study design

Non-randomised, non-controlled, interventional clinical trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Angina Pectoris, Coronary artery disease

Interventions

MSCT coronary angiography in addition to MPI

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

MSCT may improve (as compared to MPI) the diagnosis of patients presenting with chest pain complaints and an intermediate likelihood of CAD. Particularly in these patients, a non-invasive test with a high specificity (to exclude CAD) is needed to allow optimal management of patients. Currently, MPI is used for this purpose, but the specificity of MPI is suboptimal (70%).

Key secondary outcome(s)

No secondary outcome measures

Completion date

01/10/2007

Eligibility**Key inclusion criteria**

1. Adult patients (having obtained legal majority age) with chest pain complaints
2. An intermediate pre-test likelihood of CAD (based on the Diamond and Forrester method)
3. The need for additional imaging studies to evaluate the presence/absence of CAD

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Not Specified

Total final enrolment

100

Key exclusion criteria

1. Fertile women
2. Patients with severe renal failure
3. Patients presenting with a known allergy to iodine contrast media
4. Patients included in another clinical trial
5. Patients under guardianship
6. Patients whose degree of cooperation is incompatible with carrying out the study

Date of first enrolment

01/10/2004

Date of final enrolment

01/10/2007

Locations**Countries of recruitment**

Netherlands

Study participating centre

Leiden University Medical Centre (LUMC)

Leiden

Netherlands

2300 RC

Sponsor information

Organisation

Leiden University Medical Centre (LUMC) (The Netherlands)

ROR

<https://ror.org/027bh9e22>

Funder(s)**Funder type**

Charity

Funder Name

Netherlands Heart Foundation (Nederlandse Hartstichting) (NHS) (The Netherlands)

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		07/11/2006	26/03/2021	Yes	No