ISRCTN65675235 https://doi.org/10.1186/ISRCTN65675235

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 [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 26/02/2007	**Overall study status** Completed	
Last Edited 26/03/2021	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Non-randomised, non-controlled, interventional clinical trial

Primary study design
Interventional

Secondary study design
Single-centre

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
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%).

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/10/2004

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

Age group
Adult

Sex
Not Specified

Target number of participants
100

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)

Sponsor details
Department of Cardiology
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Leiden
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Sponsor type
Hospital/treatment centre

Website
http://www.lumc.nl/english/start_english.html

ROR
https://ror.org/027bh9e22

Funder(s)

Funder type
Charity

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

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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