

Minimal rest activity in a one-day stress-first myocardial perfusion imaging setting using SPECT

Published: 11-01-2016

Last updated: 19-04-2024

To determine and validate the minimal rest tracer activity for accurate diagnosis in a one-day stress-first MPI SPECT setting.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coronary artery disorders
Study type	Observational non invasive

Summary

ID

NL-OMON42543

Source

ToetsingOnline

Brief title

Minimal MPI rest activity

Condition

- Coronary artery disorders

Synonym

atherosclerotic heart disease, ischemic heart disease

Research involving

Human

Sponsors and support

Primary sponsor: Isala Klinieken

Source(s) of monetary or material Support: via exploitatie

Intervention

Keyword: Coronary artery disease, Myocard perfusion, Radiation Dose, SPECT

Outcome measures

Primary outcome

Minimal rest tracer activity for which no change in the following parameters is seen in comparison to using the reference scan. 1) Change in tracer perfusion deficit, a semi-quantitative outcome assessment, 2) change in any of the 17-segments representing the relative perfusion in the myocardium, and 3) change in defects and type of defects as observed by blinded physicians

Secondary outcome

-

Study description

Background summary

Myocardial perfusion imaging (MPI) remains important in the evaluation of patients with (suspected) coronary artery disease (CAD). Despite decades of experience and technical improvements, the tracer activity to administer in MPI using single photon emission computed tomography (SPECT) has remained the same over the years. SPECT studies consist of two tracer administrations, one during stress, and during rest. Recently, dose reductions of up to 60% of the stress injections have become feasible. In a one-day protocol a certain relation between the two injections is needed, but guidelines propose different ratios and hard evidence is lacking.

Study objective

To determine and validate the minimal rest tracer activity for accurate diagnosis in a one-day stress-first MPI SPECT setting.

Study design

Single center, diagnostic accuracy study using intra-individual comparisons of

SPECT scans.

Study burden and risks

The first 32 patients are only requested to lie in de SPECT scanner for 10 minutes instead of waiting in the waiting room.

For the last 32 patients the study will take one hour more than usual.

Moreover, an additional tracer administration - which does not have any side effects - using the already installed infuse will be administered and these patients need to lie extra in the SPECT scanner for 5 minutes. By dividing the rest activity administration over two syringes, patients do not receive any additional tracer activity. Hence, they receive the same radiation dose as patients not participating in the study.

Contacts

Public

Isala Klinieken

Dr. Van Heesweg 2
Zwolle 8025AB
NL

Scientific

Isala Klinieken

Dr. Van Heesweg 2
Zwolle 8025AB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Have undergone stress myocard perfusion imaging using SPECT and undergo a clinically indicated rest SPECT

Exclusion criteria

- No informed consent obtained
- Age < 18 years

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 10-05-2016

Enrollment: 64

Type: Actual

Ethics review

Approved WMO

Date: 11-01-2016

Application type: First submission

Review commission: METC Isala Klinieken (Zwolle)

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	NL54850.075.15