Head to head comparison between Rubidium-82 myocardial perfusing imaging with a digital and analog PET system

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To compare the image quality, visibility of perfusion deficits and myocardial blood flow of a conventional analog PET system with a digital PET system in 30 patient referred for PET myocardial perfusion imaging (MPI).

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

Summary

ID

NL-OMON44392

Source
ToetsingOnline

Brief title
ORDINATE

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: Philips,via exploitatie

Intervention

Keyword: Blood flow quantification, coronary artery disease, myocardial perfusion, Rb82 PET

Outcome measures

Primary outcome

1) The image quality scored on a four points scale, 2) The visibility of

perfusion deficits (existence, location and size) and 3) myocardial blood flow

(global and three coronary trajectories)

Secondary outcome

not applicable

Study description

Background summary

Myocardial perfusion imaging (MPI) is important in the diagnostic and prognostic evaluation of patients with (suspected) coronary artery disease (CAD). MPI is traditionally performed on single photon emission computed tomography (SPECT) but the use of positron emitting tomography (PET) is increasing due to its increased availability; higher resolution, sensitivity and specificity and the possibility of quantifying myocardial blood flow. However, high activities of the short-lived PET tracers problems negatively influence the accuracy of conventional PET systems [1]. A new PET system with digital photon counting technology may therefore be more suitable. In addition, this digital PET system has an increased temporal and spatial resolution but its effect of the image quality or visibility of perfusion deficits in MPI is still unknown [2, 3]. Isala is one of the first center globally which will be able to perform MPI on this new digital PET system and patient studies are lacking.

Study objective

To compare the image quality, visibility of perfusion deficits and myocardial blood flow of a conventional analog PET system with a digital PET system in 30

patient referred for PET myocardial perfusion imaging (MPI).

Study design

A prospective single center pilot study using intra-individual comparisons

Study burden and risks

The additional MPI PET comprises one extra visit of one hour to the nuclear medicine department at the Isala hospital in Zwolle. In this hour, patients will undergo an additional stress procedure using regadenoson (known for its limited side-effects and discomfort) and will additional Rb-82 activity resulting in an additional radiation dose of approximately 1.9 mSv. In comparison, each Dutch citizen receives around 2.5 mSv annually from the natural environment.

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 has been refered for Rb-82 PET imaging on a conventional PET
Has to be able to follow the instructions and preparations as needed for additional PET imaging
Able to lie in supine position for 40 minutes
>= 18 years of age
Has to provide written informed consent

Exclusion criteria

A potential subject in whom informed consent is not obtained or does not meet the other inclusion criteria will be excluded from participation in this study. In addition, patients requiring dobutamine for stress imaging because of intolerance of regadenoson (extremely rare) are also excluded.

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):	01-12-2017
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	21-12-2017
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	NL63853.075.17