68Ga PET/CT versus 99mTc SPECT/CT for lung perfusion and ventilation scintigraphy; a technical and practical feasibility study

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To investigate and define the most optimal technical acquisition parameters for V/Q PET/CT

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Pulmonary vascular disorders
Study type	Observational invasive

Summary

ID

NL-OMON53981

Source
ToetsingOnline

Brief title
GaTcha

Condition

- Pulmonary vascular disorders

Synonym
pulmonary embolisms

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Gallium-68, Technetium-99m, V/Q-PET/CT, V/Q-SPECT/CT

Outcome measures

Primary outcome

Investigate and define optimal image acquisition parameters for V/Q PET/CT.

Within the two patient groups, different technical parameters will be applied during image acquisition and post-processing. After enrolment of the final participant (#20) and image acquisition, all imaging studies will be presented to two independent nuclear medicine physicians, for a blinded assessment, presented in a random order. During the first assessment round; Independent physicians should grade subjective image quality according to a five-point Likert scale (ranging from very poor to very good). During a second assessment round; Independent physicians should grade image quality, compared to the current clinical standard (V/Q-SPECT). Finally, in the same round as the second assessment, physicians should report whether or not additional perfusion and/or ventilation defects could be acknowledged.

Besides subjective image quality assessment, (semi-)quantitative measurement will be performed by a medical physicist (e.g. signal-to-noise ratio, etc.)

Secondary outcome

Confirm feasibility of 68Ga-MAA and Galligas (preparation for administration and administration at the aimed time points). This will be derived from the radionuclide pharmacy (RNA) log and weekly radiopharmaceutical meetings within the department.

Confirm logistical advantages of 68Ga-V/Q-PET/CT over 99mTc-V/Q-SPECT/CT.

Differences in total acquisition times will be gathered and compared by a simple two-sided t-test; total scanning time per separate procedure (99mTc-MAA/99mTechnegas/68Ga-MAA/68Galligas) and a combination of scans (V/Q-SPECT/CT vs V/Q-PET/CT). Additionally, total procedure time will be gathered and compared in a similar fashion. Registration of both acquisition times and procedure times are standard practice and can be directly derived from the imaging archive (Sectra PACS) or medical record files (HiX, Chipsoft).

Study description

Background summary

Lung perfusion scintigraphy with 99mTc-MAA and ventilation scintigraphy with Technegas (V/Q SPECT/CT) has been the cornerstone for the detection of pulmonary embolisms (PE) for many decades. In last two decades after the introduction of pulmonary CTA, general PE detection has shifted towards CTA and V/Q SPECT/CT has become the modality of choice for specific patient populations (iodine contrast allergy, poor kidney function, pregnancy, etc.) or indications (pre-operative risk stratification, chronic embolism detection, pulmonary hypertension). V/Q SPECT/CT acquisition is performed on a gamma camera, but this technique has distinct challenges and/or disadvantages. A potential alternative is the nowadays broadly available. 68Ga as a positron emitter allows PET/CT imaging. Replacing 99mTc with 68Ga in both MAA and aerosol suspension is easy and requires no modifications. However, 68Ga-V/Q with PET/CT will resolve many of the disadvantages of V/Q SPECT/CT. Preliminary work by international colleagues and our institute have shown preparation of the radiopharmaceuticals are identical, and several international studies have proven safety and feasibility of replacing 99mTc with 68Ga. However, in our institution, clinical translation is hampered by lack of data on technical acquisition parameters for our scanners. The aim of this small study is to get more insights into technical parameters for image acquisition, logistical feasibility of V/Q PET/CT, and confirm preliminary non-inferiority of this new technique over the current clinical standard (V/Q SPECT/CT).

Study objective

To investigate and define the most optimal technical acquisition parameters for

V/Q PET/CT

Study design

Head-to-head, in-patient comparison, open label, observational cohort.

Study burden and risks

Risk of an additional V/Q PET/CT are absent, as previous clinical studies have shown no additional toxicities/adverse events following 68Galligas and 68Ga-MAA. The only expected risk entails limited additional radiation burden to the patient, 3-5 mSv (similar to V/Q SPECT/CT, but lower than pulmonary CTA). The main benefit for future patients with known or suspected PE will be of logistical nature, in which the entire investigation can be performed in 1 hour (instead of in two parts on two separate days), without increasing radiation burden or inducing toxicities. Additionally, for physicians, improved image quality (due to the intrinsic higher resolution of PET over SPECT) allows improved detection of PE and, based on the results from the previously published PECAN study, interobserver variability of subsegmental PE (the most common indication for V/Q SPECT/CT at the moment) is improved. All together, we believe the V/Q PET/CT may improve our standard clinical care, once appropriate technical parameters are defined

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

- Adult >=18 years and declared competent
- Provided written informed consent
- Referred to the Nuclear Medicine Department for a conventional V/Q-SPECT/CT
- Indication for conventional V/Q-SPECT/CT includes known or suspected pulmonary embolism

Exclusion criteria

- Pregnancy
- Children or adolescents (<18 years)

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	28-03-2023
Enrollment:	20

Type:	Actual

Ethics review

Approved WMO Date:	01-02-2023
Application type:	First submission
Review commission:	METC NedMec

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	NL83137.041.22