Assessment of localisation of vasodilatory response in CTEPH by SPECT imaging

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We aim to investigate which part of the pulmonary vasculature, the obstructed or non-obstructed, is responsible for the pulmonary vasodilator response.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Heart failures
Study type	Observational invasive

Summary

ID

NL-OMON33993

Source
ToetsingOnline

Brief title
Vasodilator response localisation in CTEPH with SPECT

Condition

- Heart failures
- Embolism and thrombosis

Synonym
chronic thromboembolic pulmonary hypertension, increased blood pressure in pulmonary vesels due to chronic pulmonary embolism

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: NWO Mozaïek beurs

Intervention

Keyword: Chornic thromboembolic pulmonary hypertension, nitric oxide, Single photon emission tomography, vasodilation

Outcome measures

Primary outcome

Macro aggregated albumin (MAA) injected in the peripheral vein distributes via the right heart (right ventricle) and pulmonary artery over both lungs; its distribution reflects the distribution of capillary perfusion at the time of injection.

The primary endpoint is the regional (lobar) change of biodistribution of MAA over both lungs under the influence of NO assessed with SPECT.
Changes in perfusion counts between obstructed and non-obstructed regions of the lungs will be assessed to determine the vasodilatory response to NO with newly developed software (based upon published algorithms). According to our hypothesis the perfusion in the nonobstructed parts will increase after inhalation of NO.

In short, to determine the effect of NO on the regional pulmonary perfusion, using quantitative analysis of the SPECT data.

Secondary outcome

To define the reproducibility of 99mTc- MAA biodistribution as assessed with SPECT another SPECT perfusion at baseline will be performed.

Study description

Background summary

Chronic thromboembolic pulmonary hypertension (CTEPH) is a disease with progressive pulmonary vascular damage that can develop after an episode of pulmonary embolism. Interestingly, during cardiac catheterization patients respond to acute pulmonary vasodilators in different degrees. However, we do not know where in the pulmonary vasculature this vasodilator response occurs.

Study objective

We aim to investigate which part of the pulmonary vasculature, the obstructed or non-obstructed, is responsible for the pulmonary vasodilator response.

Study design

This will be an experimental research. In patients with CTEPH we will perform a single photon emission tomography (SPECT) scan administering Technetium-99m (99m Tc) labelled macro-aggregated albumin (99m Tc-MAA) to determine the perfusion distribution within both lungs.

The intervention will be the application of the acute pulmonary vasodilator nitric oxide (NO). Inhaled NO will be delivered at a dose of 20 parts per million (ppm) during 5 minutes. After 5 minutes followed by injection of 99m Tc-MAA via the peripheral catheter, and subsequently followed by SPECT perfusion scanning.

Study burden and risks

Patients with the suspicion of PH and a history of pulmonary embolism referred to our hospital will be admitted for diagnostic work up for one week. They routinely undergo planar ventilation/perfusion scintigraphy combined with SPECT of the perfusion tracer. The SPECT scan takes approximately 10 minutes (20sec x 32 angles) with the patients in supine position.
For the purpose of this study, we will administer 99mTc- MAA through the peripheral line while the patients breath NO 20 parts per million (ppm) for 5 minutes. Within approximately half an hour the patients will undergo the SPECT scan. NO below 20 ppm has no adverse reaction. Doses above 20 ppm have the increased risk of methemoglobinemia and elevated nitrogen dioxide (NO2) levels. NB radiation exposure = 1.3 mSv / SPECT scan. Total amount of extra exposure for the research is 2.6 mSv. To compare, every person living in the Netherlands receives a natural background radiation dose of 2-2,5 mSv per year.

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

-mean pulmonary artery pressure > 25 mmHg during right heart catherisation/ pulmonary angiography
-specific signs of chronic thromboembolism during pulmonary angiography
-Ntric monooxide testing during pulmonary angiography cq right heart pressure measuring

Exclusion criteria

-Presence of systemic inflammation.
- Patients with pulmonary hypertension associated with collagen vascular disease, congenital heart disease, pulmonary venous hypertension, left heart failure, hypoxemic lung disease (COPD).

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	16-02-2009
Enrollment:	15
Type:	Actual

Ethics review

Approved WMO

Date:	11-02-2009
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL26314.029.08