Quantification of pulmonary vascular remodelling in pulmonary arterial hypertension patients using positron emission tomography

Published: 06-08-2014
Last updated: 21-04-2024

To non-invasively quantify pulmonary vascular remodeling in pulmonary arterial hypertension using [18F]-FLT (determination hyperproliferation).

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

Summary

ID

NL-OMON41823

Source
ToetsingOnline

Brief title
Quantification of pulmonary vascular remodelling in PAH using PET

Condition

- Pulmonary vascular disorders

Synonym
high blood pressure in the pulmonary circulation, Pulmonary arterial hypertension

Research involving
Human

Sponsors and support

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

Intervention

Keyword: FLT, PET-CT, Pulmonary arterial hypertension, Pulmonary vascular remodeling

Outcome measures

Primary outcome

Uptake pattern of [18F]-FLT of PAH patients will be compared to uptake pattern

of no-PAH controls

Secondary outcome

Not applicable

Study description

Background summary

There is a urgent need for an imaging method for the non-invasive quantification of pulmonary vascular remodeling in patients with pulmonary arterial hypertension (PAH). Characteristic features of the vascular pathology of PAH are vascular obstructions due to the presence of hyperproliferative endothelial and smooth muscle cells, increased expression of several growth factor receptors (PDGF-R, EGF-R, FGF-R). Since there is an increasing interest in the development of drugs directly targeting the pulmonary vascular remodeling, there is a need of a non-invasive quantification of the pulmonary vascular remodeling which would not only reflect the underlying disease process in PAH patients, but would also predict responses to PAH treatment.

Study objective

To non-invasively quantify pulmonary vascular remodeling in pulmonary arterial hypertension using [18F]-FLT (determination hyperproliferation).

Study design

In this pilot study we will prospectively include 8 idiopathic pulmonary arterial hypertension patients and measure the uptake patterns of the existing PET tracers [18F]-FLT in the lung. We will compare the uptake patterns of this 8 patients with existing data sets of non-PH controls.

The scan will be performed on 1 days. Scans will be performed during standard

follow-up of patients. Therefore patients dont have to be admitted to the hospital for only this study.

Study burden and risks

Venous cannulas will be placed by highly qualified medical doctors of the Department of Pulmonary Diseases. Occasionally cannulas may cause a hematoma. The total amount of blood withdrawn will be 60 ml per patient for the complete study. The total scan duration will be 70 minutes.The total amount of radiation burden will be around 6 mSv during the entire study. To compare, every person living in the Netherlands receives a natural background radiation dose of 2-2,5 mSv per year.According to the *Radiological Protection in Biomedical Research (ICRP) guidelines* which provides justification for biomedical research with ionized radiation, the level of risk related to radiation exposure, is minor to intermediate if the effective dose is below ore equal to 10mSv. No side effects are suspected of the PET tracer [18F]-FLT.

We are aware that the radiation burden for this study is high, but we think that this is acceptable for this particular study (high scientific impact). The results of this study can have great clinical benefit since there is an urgent need for an imaging method for the non-invasive quantification of pulmonary vascular remodelling which can theoretically not only reflect the primary disease process in PAH, but also predict and assess the response to treatment.

Contacts

Public
Vrije Universiteit Medisch Centrum

De Boelelaan 1117
Amsterdam 1007MB
NL
Scientific
Vrije Universiteit Medisch Centrum

De Boelelaan 1117
Amsterdam 1007MB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Idiopathic pulmonary arterial hypertension

Exclusion criteria

Left sided heart failure
Congenital heart disease
Pregnancy

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-01-2015
Enrollment:	8

Type:	Actual

Ethics review

Approved WMO Date:	06-08-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-02-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	02-09-2015
Application type:	Amendment
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	NL49166.029.14