Neurological Monitoring during pulmonary endarterectomy (PEA) and balloon pulmonary angioplasty (BPA) for chronic thrombo-embolic pulmonary hypertension (CTEPH)

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To evaluate post-operative neurologic damage using clinical data on delirium and neuropsychological testing for long term postoperative decline, in combination with measures of NfL, GFAP and Tau in CTEPH patients treated with PEA or BPA in the...

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

Summary

ID

NL-OMON54062

Source
ToetsingOnline

Brief title
NEMO CTEPH

Condition

- Pulmonary vascular disorders
- Vascular therapeutic procedures

Synonym
Chronic thromboembolic pulmonary hypertension (CTEPH), high blood pressure in the bloodvessels of the lungs due to persistent thrombosis in the pulmonary arteries

Research involving

Human

Sponsors and support

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

Intervention

Keyword: BPA, cognition, CTEPH, delirium, GFAp, neuropsychological testing, NfL, PEA, TAU

Outcome measures

Primary outcome

Post-operatiev cognitive decline (POCD) as measured by a decrease in the

adjusted score of 4 validated cognitive tests as part of a neuropsychological

evaluation at 3 and 6 months after the procedure.

Secondary outcome

Incidence of delirium in the clinical post-treatment phase.

Difference in changes of the selected neurobiomarkers (NfL, GFAP, p-tau) in

plasma of patients after undergoing either BPA or PEA.

Study description

Background summary

Chronic thromboembolic pulmonary hypertension (CTEPH) results when after treatment of an acute pulmonary embolism, persistent thrombi occur. Pulmonary endarterectomy (PEA) is the treatment of choice and can confer a near cure of the condition [1]. PEA is a complicated surgical procedure however, requiring two episodes of hypothermic cardiac arrest. A relatively high incidence of postoperative delirium and neuropsychological complications following PEA and thoracic surgery in general have been observed [2-5]. In one study, it was suggested that any surgical neurological damage was offset by beneficial effects of the postoperative hemodynamic improvement after PEA for CTEPH [6]. In recent years, a minimally invasive percutaneous procedure has become an alternative for patients who are technically inoperable. This procedure

consists of a balloon mediated local destruction of obliterative lesions in the lung vasculature (balloon pulmonary angioplasty, or BPA) and is performed by a dedicated team of a cardiologist and radiologist and is performed in awake patients [7]. As of yet there is still a paucity of data on the neurologic impact of these two procedures on the brain [6]. Neuro-biomarkers could be of novel added value in understanding these investigations.
Neurofilament light (NfL), Glial fibrillary acidic protein (GFAP) and Tau protein (Tau) have been shown to be valid markers for axonal damage, glial activation and synaptic pruning, respectively. These markers have been investigated in relation to neuronal injury, delirium and after (neuro)surgical intervention [8-11].
Analysing the post-operative cognitive decline (POCD) and supplementing this with biomarkers could improve our understanding of the extent of neurologic damage in CTEPH after PEA or BPA. Investigating such biomarkers could offer new tools for monitoring neuronal damage during cardiopulmonary bypass and hypothermic cardiac arrest.

Study objective

To evaluate post-operative neurologic damage using clinical data on delirium and neuropsychological testing for long term postoperative decline, in combination with measures of NfL, GFAP and Tau in CTEPH patients treated with PEA or BPA in the Netherlands

Study design

Prospective cohort study. CTEPH patients who are accepted for invasive treatment with BPA or PEA will have extra blood drawn (during routine clinical venapunction) at several time points during the pre- and postoperative period. This will be analysed for NfL, GFAP and Tau and analysed in relation to short term outcomes such as delirium (as measured by CAM-ICU score, DOS score and chart review) and long term outcomes such as cognitive/affective function as measured using neuropsychological testing. This will take place before PEA/BPA, and again three and six months after the last day of treatment.

Study burden and risks

The study relies on venapunction performed as part of routine clinical care. The extra blood drawn will amount to 10 ml of blood per venapunction totalling 70 ml over the course of 6 months.
The neuropsychological evaluation will take 60 minutes and be scheduled in conjunction with their routine outpatient follow-up. The patient will not need to travel to the hospital on additional dates other than those already scheduled for their care. Of the post-operative appointments, the 3 and 6 month appointment involve several hours at the hospital in between diagnostic tests

which are suited to perform the neuropsychological tests.

Contacts

Public
Vrije Universiteit Medisch Centrum

De Boelelaan 1117-1118
Amsterdam 1081 HV
NL
Scientific
Vrije Universiteit Medisch Centrum

De Boelelaan 1117-1118
Amsterdam 1081 HV
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Patients with chronic thromboembolic pulmonary hypertension undergoing pulmonary endarteriectomy or Balloon Pulmonary Angioplasty.
2. Capable of giving informed consent

Exclusion criteria

1. Severe neuropsychological comorbidity

2. Inability to provide informed consent
3. Being analphabetic
4. Insufficient understanding of the Dutch language
5. Scoring positive for dementia during the preoperative neuropsychological evaluation

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	04-12-2022
Enrollment:	70
Type:	Anticipated

Ethics review

Approved WMO

Date:	15-06-2023
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	NL76655.029.22