Cerebral Blood Flow during hemodialysis. A [15O]H2O PET-CT pilot study comparing cerebral blood flow before, during and after hemodialysis

Published: 10-02-2015
Last updated: 21-04-2024

To study the acute effect of HD on global and regional CBF.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Structural brain disorders
Study type	Observational invasive

Summary

ID

NL-OMON42190

Source
ToetsingOnline

Brief title
Cerebral Blood Flow during hemodialysis.

Condition

- Structural brain disorders
- Renal disorders (excl nephropathies)

Synonym
blood supply to the brain

Research involving
Human

Sponsors and support

Primary sponsor: Interne geneeskunde, Nefrologie
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: cerebral blood flow, hemodialysis, PET

Outcome measures

Primary outcome

1. the change in total and regional CBF during the study session as assessed by

PET-CT scan.

2. the change in rSO2 during the study session as assessed by NIRS, and it's

correlation with the PET-CT scan estimates

Secondary outcome

Change in regional and total CBF correlated to

a. structural cerebral lesions on MRI (e.g. white matter lesions)

b. outcomes of cognitive testing.

Study description

Background summary

Hemodialysis (HD) initiation in patients aged >=75 years has doubled the last decade. Especially in elderly, intradialytic hypotension (IDH) is commonly observed as a clinical sign of hemodynamic stress. The hemodynamic changes during HD induce a significant fall in myocardial blood flow that may lead to cardiac ischemia. Likewise, the hemodynamic stress of HD may affect cerebral blood flow (CBF) and, if repetitive, may induce cerebral ischemic damage and may negatively affect cerebral (cognitive) function. Several arguments favor this pathophysiological hypothesis.
First, cognitive performance in HD patients is best one hour before or one day after HD and deteriorates during a HD session. Second, long-term blood pressure variability has been associated with increased risk of cardiovascular events, stroke, worse cognitive performance, lower hippocampal volume and a risk of cortical infarcts, in older people independent of the average absolute blood pressure level. In HD patients, incidences of cerebral ischemia, subclinical brain damage, cerebral atrophy and cognitive impairment are higher compared to the general population. Stroke incidence strongly rises in the first month

after HD initiation in elderly patients and remains elevated afterwards compared with the period before HD was started. This might be related to the repetitive hemodynamic changes during HD. Third, earlier studies that investigated CBF in HD patients found that age, anemia, duration of HD therapy and duration of hypertension are important factors influencing CBF in these patients. Regional CBF was decreased in the frontal cortex and white matter, and this was most pronounced in patients with a higher dialysis vintage.
We hypothesize that HD-induced blood pressure changes may lead to a fall in global and/or regional cerebral blood flow during HD. On the long term, these repetitive blood pressure changes may cause chronic ischemia, mainly because cerebral autoregulation that normally preserves the CBF to protect the brain is likely to be impaired in these patients. Previous studies on the effect of HD on CBF, using various methods, have yielded conflicting results. [15O]H2O PET is currently the gold standard to measure CBF. This method has not been used for the evaluation of CBF during a HD session. Near-infrared spectroscopy (NIRS) will be used to measure local cerebral tissue regional oxygen saturation (rSO2). NIRS is an easy method to perform during a HD session and gives additional information about cerebral oxygen changes during HD, which are related to CBF.

Study objective

To study the acute effect of HD on global and regional CBF.

Study design

Cross-sectional study.

Study burden and risks

For the combined HD and PET-CT session patients will have to stay in the hospital for 120 minutes longer than usual for their regular HD treatment. Two dialysis needles will be inserted in the arterio-venous fistula but these needles would also have to be inserted without participating in the study. For the PET-CT scan a peripheral venous catheter will be placed in the non-arteriovenous fistula arm for administration of [15O]H2O. Each patient will undergo 3 PET-CT scans of the cerebrum during a single HD session and will experience the inconvenience of lying in the PET-CT camera for about 50 minutes. The total radiation exposure from radiopharmaceuticals is 3.35 mSv (3600 MegaBequerel (MBq)) per patient for the total study.

Participating patients will further undergo: 1. A 1.5 Tesla MRI scan; 2. A bilateral carotid artery duplex echosonography (neurology policlinics); 3. NIRS during the study session with two self-adhesive pats on the forehead; 4. Cognitive testing; 5. Blood pressure and heart rate measurement at 30-min intervals, and immediately before and after each PET-CT scan, which is, in

part, usual care; 6. Arterial blood sampling during the PET-CT study session will be drawn from the shunt for continuous arterial input during each PET scan and separate blood will be drawn 3 times for laboratory measurements as part of usual care. For the continuous arterial input, arterial blood will be sampled by a dedicated programmable blood-sampler to obtain the radioactivity concentration in blood during the scan. For all 3 PET scans together the total arterial blood volume will not exceed 110 ml. For the whole study the total blood volume will not exceed 150 ml. We believe it is justified to perform the proposed study in order to elucidate the possible effects of HD on CBF given the scarcity of data on the background of high stroke rates and an increased prevalence of cognitive impairment in HD patients, especially in elderly. Identification of possible changes in (regional) CBF may, first, help to understand which pathways are involved in the pathophysiology of brain damage in HD patients that leads to comorbidity and decreased quality of life, especially in elderly HD patients. Second, this study may help develop dialysis protocols that better preserve CBF and function. Patients will be informed regarding accidental findings at the MRI scan or significant asymptomatic carotid artery stenosis (>70%) that will need medical care.

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

Patients aged 65 years or older on maintenance hemodialysis, of which at least 6 patients for a longer period of time (>1years). The patients must have an arteriovenous fistula without recirculation as established by routine Transonic flow measurements. The hemoglobin value should be in the target range 6.2- 8 mmol/l since at least 1 month.

Exclusion criteria

1. The absence of informed consent. 2. Diagnosis of dementia, hydrocephalus, history of raised intracranial pressure, significant (>70%) carotid artery stenosis, end stage liver disease. 3. Actively treated cancer. 4. Actual hospital admission at timing of HD study session. 5. Cochlear implants. 6. Claustrophobia. 7. MRI incompatible implants in the body (including prosthetic heart valves). 8 Pacemakers. 9. Subcutaneous insulin infusion pomp. 10. Any risk of having metal particles in the eyes due to manual work without proper eye protections. 11. Tatoos containing red pigments that form a safety risk. 12. The refusal to be informed of significant carotid artery stenosis (duplex) or structural brain abnormalities (MRI) that could be detected during the study.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-04-2015

Enrollment:	14
Type:	Actual

Ethics review

Approved WMO Date:	10-02-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
ClinicalTrials.gov	NCT02272985
CCMO	NL48969.042.14