Pulsatility in cerebral perforating arteries in patients with lacunar infarction or deep hemorrhage, an explorative 7T MRI study.

Published: 12-06-2015
Last updated: 19-04-2024

Explore difference in perforating artery pulsatility index between two patients groups with small vessel disease (history of lacunar infarct and deeply located haemorrhage) and healthy controls.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Central nervous system vascular disorders
Study type	Observational invasive

Summary

ID

NL-OMON44727

Source
ToetsingOnline

Brief title
PULSATE

Condition

- Central nervous system vascular disorders

Synonym
deep intracerebral hemorrhage/hemorrhagde in the deep structures of the brain., lacunar infarction/small deep infarction

Research involving
Human

Sponsors and support

Primary sponsor: Divisie Beeld, afdeling Radiologie
Source(s) of monetary or material Support: This research received funding from the European Research Council under the European Union's Seventh Framework Programme (FP7/2007-2013) / ERC grant agreement n°337333

Intervention

Keyword: cerebral perforating artery, deep intracerebral hemorrhage, lacunar infarction, pulsatility

Outcome measures

Primary outcome

Difference in pulsatility of cerebral perforating arteries between patients and

healthy controls.

Secondary outcome

N.A.

Study description

Background summary

Recently, we developed a novel and promising MRI technique that assesses the pulsatile blood flow velocity in small cerebral perforating arteries. Increased blood flow pulsation is hypothesized to be in the causal pathway of many cerebrovascular pathologies of the smaller vessels. Our simulations suggest that, with 7T MRI, we can measure the blood flow pulsatility index (PI) in vessels with a diameter of 80 microns and larger. Until now, doppler ultrasound and lower field MRI have been used to measure PI, but can only do so up to the large intracerebral vessels. Many cerebrovascular pathologies arise at the level of much smaller arteries. Therefore, it is important to investigate the new small vessel PI marker in relevant patient groups. We will investigate two patient groups with cerebrovascular disease of small intracerebral arteries. The first patient group we will study consists of patients with lacunar infarction (which are known to have a different pulsatility index (PI) of the larger vessels) and the second group consists of patients with a history of deep hemorrhages (which are associated with hypertension, and thus to changes

in PI).

Study objective

Explore difference in perforating artery pulsatility index between two patients groups with small vessel disease (history of lacunar infarct and deeply located haemorrhage) and healthy controls.

Study design

Because pulsatility in perforating cerebral arteries has not been studied before, this will be an explorative observational study. The study will have a case control design with two patient groups and a control group.

Study burden and risks

Negligible low risk study with low burden.

Contacts

Public
Selecteer

Heidelberglaan 100
Utrecht 3508 GA
NL
Scientific
Selecteer

Heidelberglaan 100
Utrecht 3508 GA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Lacunar infarction group:
- Clinical lacunar stroke confirmed by imaging, in the last 5 years.
Deep ICH group:
- Deep spontaneous ICH, compatible with so-called hypertensive hemorrhage or ICH due to SVD, confirmed by imaging, in the last 5 years.
Healthy control group:
- No history of stroke, transient ischemic attack or cognitive impairment.

Exclusion criteria

All groups:
- WHO performance status score * 2. (independent mobility and living)
- Currently hospitalized.
- MRI contraindications per clinical practice, such as (possible) pregnancy and metal or electronic implants not compatible with (7T) MRI.
Control group:
- When study images for a control subject as a chance finding show confluent white matter hyperintensities (Fazekas scale > 2), lacunes or ICH the control will be excluded and replaced.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	31-03-2016
Enrollment:	55
Type:	Actual

Ethics review

Approved WMO Date:	12-06-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	14-06-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL52997.041.15