The dynamic effects of hypertension on the brain and its vessels

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

Summary

ID

NL-OMON45503

Source
ToetsingOnline

Brief title
DynaBrain

Condition

- Central nervous system vascular disorders
- Vascular hypertensive disorders

Synonym
Hypertension; High bloodpressure

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: VIDI beurs J.Hendrikse

Intervention

Keyword: Anti-hypertensive medication, Diurnal fluctuations, Hypertension, Magnetic resonance imaging

Outcome measures

Primary outcome

The main study parameters are the structural and functional MRI differences

between baseline and follow-up scans (both 3T and 7T MRI).

Secondary outcome

The secondary study parameters are the structural and functional MRI

differences between patients and healthy volunteers.

The tertiary study parameters are the difference between morning and evening

total brain volumes, CSF volumes, and perfusion status as measured with 3T MRI.

The quaternary study parameter/endpoint is the clinical consequences of

hypertension as measured with neuropsychological tests.

Study description

Background summary

High blood pressure and specifically hypertension affects many people in the population and is the largest contributor to global mortality. Moreover hypertension has many devastating consequences ranging from kidney failure to stroke and death. The damage caused by hypertension gradually evolves and is often found when damage already happened. Despite these consequences, it is poorly understood how hypertension is initiated and what the global consequences are of hypertension on the brain and vessels, also on a diurnal level. Furthermore midlife high blood pressure is a well-known risk factor for cerebrovascular diseases, ultimately leading to cognitive decline at an older

age. As such, antihypertensive medication is suggested to be protective for cognitive brain changes.

Recent research in mice showed that sleep is important for restoring the brain. During our night-time the interstitial space increased with more than 60% resulting in better perfused tissue by CSF. The exchange of interstitial fluid and CSF enables toxins and waste products of metabolites to be drained from the brain into the perivascular spaces and ultimately into the lymphatic system. This brain drainage system is now known as the *glymphatic system*. It is indicated that the glymphatic function is suppressed in various disease. This reduction in function may lead to accumulation of protein aggregation and seems to follow the day-night cycle. Even so, failure of the drainage system may contribute to the development of neurodegenerative disease, but also to brain injury and stroke. Since we know that this system exists it may be hypothesized that differences in brain volume and CSF may be found between day and night-time as a result of different glymphatic activity. One of the diseases suggested to be affecting the glymphatic system is stroke. Since hypertension is the utmost important risk factor of stroke and glymphatic function probably fails in stroke, it may be suggested that hypertension directly acts on this system.

Study objective

Our research aim is fourfold:
1) We aim to assess the effect of hypertension on functional and structural markers of the brain using 3 tesla (T) and 7T MRI in patients who are temporary drug naïve and will be switched-on to medication as part of their regular clinical work-up.Therefore baseline scans (without medication) will be compared to follow-up scans (with medication) in patients.
2) Functional and structural markers of the brain in patients at baseline will be compared to these markers in healthy volunteers at baseline using 3T and 7T MRI.
3) In a subset (1/3) of patients and (1/3) healthy volunteers we will also assess the circadian rhythm of these functional markers using 3T MRI.
4) To obtain a basic understanding of the possible clinical and subclinical consequences of hypertension, we will also perform neuropsychological tests in all subjects.

Study design

This study is designed as a single-center prospective case-control study. MR imaging at baseline and after three months will be performed with a 3T MRI system in patients with hypertension who are temporary medication naïve as part of their regular clinical care. A second MRI exam will be performed at 7T, also at baseline and after three months. In healthy volunteers only the baseline scans (one at 3T and one at 7T) will be obtained. One third of the volunteers

will be asked to come back in the afternoon for an additional 3T MRI to obtain information about circadian rhythms.

Baseline characteristics of all subjects will be collected during inclusion of this study. 3T MRI exams will be acquired before the start of medication and within three months when patients are switched-on antihypertensive medication as part of their regular clinical care. 7T MR imaging will be performed within one week after the first and second 3T MRI scan. A third of the volunteers will be asked to come back in the afternoon for an additional 3T MRI to obtain information about circadian rhythms.

The radiologist and a second (scientific) observer will be blinded for clinical information.

Study burden and risks

During the MRI, patients are exposed to strong magnetic fields and radio waves. In normal clinical practice, MRI is very
often used. There are no harmful effects on the human body determined. In some cases, people experience flashes of
light, tingling and transient dizziness. These are always during the scan and disappear immediately after scanning.
Implanted medical devices might become disturbed by the magnetic field. People with medical implants are therefore
not considered for the study.

Contacts

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584 CX
NL
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584 CX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Inclusion criteria

Inclusion criteria for patients with hypertension:
• 18 years and older
• Hypertension >140/90 mm Hg at inclusion.
• Patients must be part of the *zorgpad hypertensie*. These patients are temporary drug naïve and are switched on to medication after two weeks of being drug naïve as part of this *zorgpad hypertensie*.;Inclusion criteria for healthy volunteers:
• 18 years and older

Exclusion criteria

Exclusion criteria for patients with hypertension:
• Impossibility to undergo MRI (claustrophobia, implants or metal objects in or around the body)
• Pregnancy
• Non-Dutch speaking
• Illiterate;Exclusion criteria for healthy volunteers:
• Impossibility to undergo MRI (claustrophobia, implants or metal objects in or around the body)
• Pregnancy
• Treated with antihypertensive medication
• Non-Dutch speaking
• illiterate

Study design

Design

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

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-08-2018
Enrollment:	200
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	28-12-2017
Application type:	First submission
Review commission:	METC NedMec

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	NL59808.041.17