Hypertension, Small Vessel Disease (SVD) and cognitive function.

Published: 22-07-2009
Last updated: 06-05-2024

1) to investigate whether hypertensive patients with WMLs decline more strongly in cognitive function than hypertensive patients without WMLs in a 4-year time period. 2) to identify predictors for cognitive dysfunction in hypertension/SVD patients...

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

Summary

ID

NL-OMON39508

Source
ToetsingOnline

Brief title
Hypertension, Small Vessel Disease (SVD) and cognitive function.

Condition

- Central nervous system vascular disorders
- Cognitive and attention disorders and disturbances
- Vascular hypertensive disorders

Synonym
hypertension related. silent brain damage due to elevated blood pressures, silent cerebrovascular disease

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: De Weijerhorst

Intervention

Keyword: Brain damage, Cognitive function, Hypertension, Small Vessel Disease

Outcome measures

Primary outcome

The degree of SVD (WMLs, LACIs, and BMBs) and cognitive functioning.

Secondary outcome

Haptoglobin polymorphism and EPC-activity.

Other cerebral abnormalities observed by MRI: atrophy and other cerebral

abnormalities.

Study description

Background summary

Hypertension is a major risk factor for cerebral small vessel disease (SVD) (Spence, 1996), which causes white matter lesions (WML), small deep subcortical ischemic lesions (lacunar infarcts, LACI) (Pantoni, Poggesi, & Inzitari, 2007) and brain microbleeds (BMBs) (Henskens, van Oostenbrugge, Kroon, de Leeuw, & Lodder, 2008). WMLs, in particular located periventricularly, predict cognitive decline and conversion to dementia (Debette et al., 2007). Although hypertension constitutes a major risk factor in SVD and the related cognitive decline, it cannot account for all the risk (Vermeer, Longstreth, & Koudstaal, 2007). Therefore, other risk factors need to be investigated in order to disentangle the complex model of the pathogenesis of SVD-mediated cognitive decline. Effects of the haptoglobin polymorphism (Staals et al., 2008) and EPC-activity (Rouhl) on WMLs have been found recently. In this study, we would like to explore the associations of these variables with cognition.
It is expected that hypertension indirectly influences the degree of cognitive dysfunction, and is mediated by the extent of SVD. It is expected that more severe hypertension is associated with more severe SVD, which in turn is negatively related to cognitive functioning. The relation of the haptoglobin polymorphism and EPC-activity with cognition will be explored.

Study objective

1) to investigate whether hypertensive patients with WMLs decline more strongly

in cognitive function than hypertensive patients without WMLs in a 4-year time period.
2) to identify predictors for cognitive dysfunction in hypertension/SVD patients.

Study design

Prospective, observational, follow-up cohort study

Study burden and risks

Patients undergo non-invasive magnetic resonance imaging (MRI) of the brain and a neuropsychological assessment. The choice of the study group is essential since these patients may have a wide range of SVD-related brain damage (from none to extensive WMLs, LACIs and BMBs), but still are a-symptomatic. Since WMLs, LACIs and BMBs cannot be undone, but the possible risk factors of this SVD (a.o. hypertension) can be treated, it is of clinical relevance to study the role of these risk factors.

Contacts

Public
Medisch Universitair Ziekenhuis Maastricht

P.Debyelaan 25
Maastricht 6229 HX
NL
Scientific
Medisch Universitair Ziekenhuis Maastricht

P.Debyelaan 25
Maastricht 6229 HX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Inclusion criteria
- Patients who participated in the HYBRiD- study
- Consent for being contacted for follow-up studies
- Essential hypertension:
o Use of antihypertensive medication at first visit of the hypertension clinic, or
o Office blood pressure: *140 and/ or *90 mmHg (average of 3 measurements with intervals of 2 minutes minimum, or
o ABPM blood pressure: *125 and/ or *80 mmHg (average of 24 hours).
- Caucasian
- Age between 18 and 90 years
- Ambulant

Exclusion criteria

- - Cerebrovascular abnormalities in anamnesis
o TIA in 6 months before anamnesis
o Brain infarction
o Haemorrhage (subarachnoid or intracerebral)
- Contra indications for MRI
o Heart valve prosthesis
o Pacemaker
o Intracerebral clips (aneurysm)
o Intra-ocular metal pieces
o Cochlear implant
o Claustrophobia
- When the patient does not appreciate to receive the results of the study, in particular if abnormalities are found during MRI or neuropsychological assessment, which are of great importance for the patients health.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-08-2009
Enrollment:	190
Type:	Actual

Ethics review

Approved WMO Date:	23-07-2009
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	18-09-2013
Application type:	Amendment
Review commission:	MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht)
Approved WMO Date:	19-05-2014
Application type:	Amendment
Review commission:	MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht)

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	NL24559.068.09

Study results

Date completed: 01-09-2015

Actual enrolment: 112