Do you mind standing?
The impact of orthostatic hypotension on cerebral perfusion and function in autonomic failure

Published: 27-07-2012
Last updated: 26-04-2024

To assess the impact of OH on cerebral perfusion and function in severe OH in AF (n=10) and healthy controls (n=10).

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

Summary

ID

NL-OMON38420

Source
ToetsingOnline

Brief title
impact of orthostatic hypotension on cerebral function

Condition

- Structural brain disorders

Synonym
autonomic failure, low blood pressure

Research involving
Human

Sponsors and support

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

Intervention

Keyword: autonomic failure., cerebral perfusion, orthostatic hypotension

Outcome measures

Primary outcome

The main outcome measure is the change in total SART error score in the

standing vs. the supine position.

Secondary outcome

changes in cerebral perfusion and bloodpressure upon standing.

Study description

Background summary

Orthostatic hypotension (OH) affects up to 30% of all elderly people and is associated with the development of white matter lesions, stroke and vascular dementia. These findings suggest that OH may cause permanent sequelae through cerebral hypoperfusion. Supporting this view, orthostatic cognitive impairment is a common symptom of severe OH due to autonomic failure (AF). Studying orthostatic cognitive and circulatory changes may prove fruitful to elucidate the pathophysiology of OH-related cerebral damage.

Study objective

To assess the impact of OH on cerebral perfusion and function in severe OH in AF (n=10) and healthy controls (n=10).

Study design

Single center, observational pilot study.

Study burden and risks

All measurements are non-invasive and without discomfort. Standing may elicit syncope. Given the short duration of the standing test, the risk for syncope is low. The participants are instructed to report prodromal symptoms of syncope, so they can be seated; hereby loss of consciousness can be prevented. In

addition, the investigator can intervene in case the BP measurements are decreasing and thus a syncopal reaction is expected.

Contacts

Public
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2300 RC
NL
Scientific
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2300 RC
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Both groups (autonomic failure, controls):
- Age> 18 year
Autonomic failure:
- Symptomatic orthostatic hypotension

Exclusion criteria

both groups:
- MMSE <24;-Controls:
- Diabetes type 1 or 2
- Parkinson's disease
- heartfailure
- complaints of Orthostatic hypotension

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):	03-08-2012
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	27-07-2012
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL35521.058.12