Autonomic function in Alzheimer: assessment using tilt-table testing

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

Summary

ID

NL-OMON50891

Source
ToetsingOnline

Brief title
Autonomic function in Alzheimer

Condition

- Central nervous system vascular disorders
- Dementia and amnestic conditions
- Vascular hypertensive disorders

Synonym
Cognitive impairment, memory complaints

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Alzheimer's Disease, Autonomic function, Mild Cognitive Impairment, Tilt-table test

Outcome measures

Primary outcome

The primary study parameter is autonomic function (cardiovascular measures of autonomic function derived from continuous BP and ECG signals) during HUTT in MCI/AD vs control.

Secondary outcome

Secondary parameters will be effects of changes in BP on CBF; differences in complexity measures in cardiovascular and cerebrovascular signals (BP, ECG, CBFV and NIRS) in rest and during HUTT between MCI/AD and controls.

Study description

Background summary

There are indications that autonomic function is affected in patients with Alzheimer. To investigate autonomic function in Alzheimer, prolonged head-up tilt-table testing (HUTT) will be applied. During HUTT the autonomic nervous system is challenged, specifically baroreflex function. Cardiovascular and cerebrovascular signals will be measured to determine autonomic control of heart rate and blood pressure (BP) and to determine the effect of any changes in BP on cerebral blood flow. These signals include continuous BP, electrocardiography (ECG), transcranial doppler (TCD) and near-infrared spectroscopy (NIRS). It has been hypothesized that AD is associated with autonomic dysfunction. We will investigate this in patients with symptomatic Alzheimer*s disease, i.e. in patients with Mild Cognitive Impairment (MCI) and Alzheimer*s Disease dementia (AD). In addition to traditional linear analyses, complexity analyses will be explored in this study. Due to the complex intertwined underlying physiological processes, looking at complexity analyses instead of traditional linear measures, such as mean and standard deviation, could result in innovative ways to assess impaired autonomic function.

Study objective

The primary objective is to determine if there is a difference in autonomic function between patients with Alzheimer*s disease (MCI and AD) and a matched control group. The secondary objectives will be explorative and aimed to investigate cardiovascular and cerebrovascular complexity measures in patients with MCI and AD. Other objectives will be to determine the added value of complexity measures compared to traditional linear measures, such as the mean and standard deviation.

Study design

Explorative study to assess cardiovascular and cerebrovascular parameters in MCI and AD as measures of autonomic function during prolonged HUTT.

Study burden and risks

All measurement techniques and test procedures are non-invasive. Individuals can only feel discomfort due to presyncope symptoms. All participants will be asked to visit the lab once. This places only a minor burden on participants. There will be no direct benefits for participants, with the exception that a finding of autonomic impairment could result in medical advice to the general practitioner and/or geriatrician. The knowledge obtained in this study will contribute to a better understanding of autonomic function in AD, which can translate into knowledge about the risks of dizziness and syncope in this population, and inform the treatment of cardiovascular diseases (e.g. hypertension) in this population. The knowledge obtained will also contribute to our understanding of AD, which is a complex, multicausal disease.

Contacts

Public
Radboud Universitair Medisch Centrum

Reinier Postlaan 4
Nijmegen 6525 GC
NL
Scientific
Radboud Universitair Medisch Centrum

Reinier Postlaan 4
Nijmegen 6525 GC
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Clinical diagnose of Mild Cognitive Impairment (MCI) or Alzheimer's Disease (patient group)
Normal age-related cognitive functioning (control group)
Age 55 yrs and over

Exclusion criteria

Bodyweight of >180 kg.
History of severe cardiovascular and neurological disorders, traumatic brain injury, mental retardation or muscle disorders.
Use of cholinesterase inhibitors or Memantine.
Contraindicators of HUTT.
Subjects who cannot stand up actively by themselves or are immobile.

Study design

Design

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

Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-05-2021
Enrollment:	75
Type:	Actual

Ethics review

Approved WMO Date:	20-04-2021
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	03-08-2021
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL76439.091.21