Follow-up of cognition and cerebral hemodynamics in older adults with normal cognitive function and older adults with Mild Cognitive Impairment

Published: 25-11-2019
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To explore the relation between (changes in) cerebrovascular function and the change in cognitive function in older adults with and without MCI across follow-up.

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

Summary

ID

NL-OMON48116

Source
ToetsingOnline

Brief title
Cognition and cerebral hemodynamics in healthy aging and MCI

Condition

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

Synonym
cognitive impairment; cerebrovascular dysfunction

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: Cognition, Follow-up, Hemodynamics, Physical activity

Outcome measures

Primary outcome

The change in cerebrovascular and cognitive function between the post-intervention measurements from the previous studies and the measurements from this follow-up study. Cognitive function will be assessed by comprehensive neuropsychological testing involving the tests listed in the protocol of the study in which each individual participated in (either NL54544.091.15 or NL19014.091.07). Cerebrovascular function measures will consist of cerebral autoregulation and cerebral vasomotor reactivity.

Secondary outcome

The (change in) physical fitness will be assessed using a submaximal incremental cycling test, hand grip strength test, 30 second chair stand test, and a physical activity questionnaire (LAPAQ).

Other study parameters include clinical data on progression of cognitive impairment (new onset of MCI, changes in severity of MCI, progression to Alzheimer*s disease or dementia) or development of other diseases or comorbid conditions.

Study description

Background summary

Cardio- and cerebrovascular diseases remain one of the leading causes of morbidity and mortality in the modern world, with coronary artery disease and cerebrovascular accidents as the top manifestations. Atherosclerosis is the underlying pathological mechanism for these diseases, and poses a diagnostic challenge due to its long asymptomatic phase characterized by progressive endothelial dysfunction eventually leading to the development of atherosclerotic plaques. In line with the process and development of coronary artery disease, endothelial dysfunction has also been implicated in early cognitive changes and is associated with mild cognitive impairment in older adults, as well as increased severity of cognitive impairment in patients at increased risk for dementia.
Mild cognitive impairment (MCI) represents a transition state between typical age-related cognitive changes and progressive cognitive decline, possibly leading to Alzheimer*s disease (AD). Older adults diagnosed with MCI progress to AD at a much higher rate than healthy age-matched peers. However, a portion of those diagnosed with MCI remain stable and do not develop AD, which poses an additional prognostic challenge in this vulnerable population. Past year, increasing evidence has linked changes in cerebrovascular function and/or cerebral perfusion to the process of cognitive decline. For example, MCI patients show impairments in cerebrovascular function when compared to age-matched healthy peers, and may decline at a higher rate such that these two groups exhibit different trajectories of both cognitive and cerebrovascular decline. More specifically, aging and MCI status have been linked to impaired cerebrovascular properties, such as the dilator/constrictor response to changes in blood pressure (cerebral autoregulation, CA) and to changes in PaCO2 (vasomotor reactivity CVMR).
An important limitation of previous work is that it had a cross-sectional design, making it difficult to link older age and/or MCI to changes in cerebrovascular function or cerebral blood flow. Past years, we have performed studies in older subjects and those with MCI, including comprehensive assessment of cerebrovascular and cognitive function. By repeating these measurements, the time between follow-up measurements allow us to provide unique insight and examine the longitudinal relationship between (changes in) cognitive and cerebrovascular function in older adults with and without MCI. Since comprehensive assessment was performed, we can tightly control our outcomes for potential factors known to influence cerebrovascular and/or cognitive function (e.g. physical fitness, physical activity patterns).

Study objective

To explore the relation between (changes in) cerebrovascular function and the change in cognitive function in older adults with and without MCI across follow-up.

Study design

Observational follow-up.

Study burden and risks

Possible disadvantages/burden associated with participation:
- Placed measurement equipment can be experienced as uncomfortable.
- Discomfort when placing the hand in ice water.
- Fatigue during and after the incremental cycling test.

Contacts

Public
Radboud Universitair Medisch Centrum

Philips van Leydenlaan 15
Nijmegen 6525 EX
NL
Scientific
Radboud Universitair Medisch Centrum

Philips van Leydenlaan 15
Nijmegen 6525 EX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Participated in one of our previous two studies (NL19014.091.07 or

NL54544.091.15);
- Informed consent;
- Adequate visual and auditory acuity to allow neuropsychological testing;
- Caregiver/informant available (applicable to cognitively impaired patients).

Exclusion criteria

- Participants currently enrolled in any investigational drug study.

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):	03-01-2020
Enrollment:	90
Type:	Actual

Ethics review

Approved WMO Date:	25-11-2019
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	16-12-2019
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Approved WMO Date:	30-01-2020
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	NL71569.091.19

Study results

Date completed:	14-04-2022
Actual enrolment:	46

Summary results
Trial ended prematurely