Vascular Phenotypes in a Geriatric Population

Published: 03-11-2021
Last updated: 08-07-2024

Our hypothesis is that patients with micro and macrovascular potentially have a different geriatric profile (cognitive function, physical function, ADL dependency, negative outcomes)

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON29291

Source
Nationaal Trial Register

Brief title
VARIATION

Health condition

Memory complaints, microvascular damage, macrovascular damage

Sponsors and support

Primary sponsor: Amsterdam University Medical Center
Source(s) of monetary or material Support: partly bij Alzheimer Nederland

Intervention

Outcome measures

Primary outcome

The main study parameters are different vascular phenotypes, based on measurements of macro- and microvascular function.

Secondary outcome

Secondary study parameters are cognitive functioning, as assessed by neuropsychological assessment, physical performance (handgrip strength, gait speed and Short Physical Performance Battery) and functional outcomes: activities of daily living (ADL) and instrumental ADL (iADL) dependence levels, quality of life, (serious) adverse events and mortality.

Study description

Background summary

Rationale: There is a strong relationship between cardiovascular morbidity and the risk of functional decline. However, the effect of cardiovascular morbidity on cognitive and physical function in geriatric memory clinic patients is not precisely known. Objective: to relate different vascular phenotypes, based on macro- and microvascular damage to changes in cognitive and physical status in a geriatric population. Study design: observational longitudinal cohort study with a follow-up of 2 years.

Study objective

Our hypothesis is that patients with micro and macrovascular potentially have a different geriatric profile (cognitive function, physical function, ADL dependency, negative outcomes)

Study design

baseline, 6 months, 12 months, 24 months.

Contacts

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Eligibility criteria

Inclusion criteria

- Age of 65 years or older - Signed informed consent for the general protocol (METc 2017.148)

Exclusion criteria

- Insufficient proficiency of the Dutch language. - Severe cognitive impairment: MMSE score < 16.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	03-11-2021
Enrollment:	150
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion
Date: 03-11-2021
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 52796
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL9856
CCMO	NL73405.029.20
OMON	NL-OMON52796

Study results