The Heart-Brain Study: the missing link in the pathophysiology of vascular cognitive impairment

Published: 16-06-2014
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We aim to assess the association between (cardio-)vascular and hemodynamic factors in relation to cognitive function.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Heart failures
Study type	Observational invasive

Summary

ID

NL-OMON50275

Source
ToetsingOnline

Brief title
the Heart-Brain Study

Condition

- Heart failures
- Dementia and amnestic conditions
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
vascular cognitive impairment, vascular dementia

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Cardiovasculair onderzoek Nederland

(CVON)

Intervention

Keyword: carotid occlusive disease, cerebral perfusion, heart failure, vascular cognitive impairment

Outcome measures

Primary outcome

Cognitive functioning as measured by severity of cognitive impairment on the

Clinical Dementia Rating Scale, the MMSE, 15 word verbal learing test

(15-WVLT), Stroop interference test, Trail making test, digit span test and the

Category fluency test.

Secondary outcome

Structural and functional brain MRI, cerebral perfusion on MRI, daily

functioning as measured by the Amsterdam IADL Questionnaire and Disability

Assessment of Dementia, symptoms of depression as measured with the 15-item

Geriatric Depression Scale, symptoms of apathy as measured with the Starkstein

Apathy Scale.

Study description

Background summary

Cardiovascular diseases are increasingly recognized as an independent cause of and contributor to cognitive decline. Patients with vascular cognitive impairment (VCI), carotid occlusive disease (COD) and patients with heart failure (HF) each represent a dysfunction of part of the heart-brain axis. Available data suggest that hemodynamic balance in the heart-brain axis is crucial in maintaining functional and structural integrity of the brain and thereby cognitive functioning. More research is necessary to more precisely establish the relation between hemodynamic abnormalities, possibly mediated through altered brain structure and perfusion, and vascular cognitive

impairment.

Study objective

We aim to assess the association between (cardio-)vascular and hemodynamic factors in relation to cognitive function.

Study design

Prospective observational multicenter study with a follow up period of two years. All subjects will undergo the same standardized set of clinical, neuropsychiatric and imaging tests to assess cardiovascular risk factors and disease, structural and functional brain and cardiac status, cognitive dysfunctioning, daily functioning and presence of neuropsychiatric symptoms. After two years assessment of daily functioning and neuropsychiatric symptoms including cognitive function and brain MRI will be repeated.

Study burden and risks

All research data are collected through standard medical procedures and no experimental intervention is conducted. The additional risk of this study is considered negligible. The burden of participation consists of time investment at both baseline and follow up (120 minutes for clinical assessment and neuropsychological testing, a maximum of 60 minutes for MRI scanning) and the fact that a venous blood sample is required. However, this study will contribute to knowledge of hemodynamic factors associated with cognitive decline which form possible targets for future therapy.
Addendum January 2015: In the MRI study the contrast agent gadolinium was added to the. This may change the risk classification.

Contacts

Public
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333 ZA
NL
Scientific
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333 ZA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients with vascular cognitive impairment with MMSE >< = 20, carotid occlusive disease of heart failure are included. Further inclusion criteria are age 50+ years, able to undergo cognitive testing, independence in daily life.

Exclusion criteria

Contraindication for magnetic resonance imaging (MRI) testing

Study design

Design

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

Primary purpose: Basic science

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	05-09-2014
Enrollment:	750
Type:	Actual

Ethics review

Approved WMO Date:	16-06-2014
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	14-04-2015
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	24-11-2015
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	19-02-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	03-04-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	27-07-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	12-02-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL46484.058.13