Risk factors and consequences of atrophy of the hippocampal formation in patients with manifest arterial disease: the SMART-Medea study

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

Summary

ID

NL-OMON37630

Source
ToetsingOnline

Brief title
Hippocampal atrophy in patients with manifest arterial disease

Condition

- Structural brain disorders
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
cognition, hippocampal atrophy

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Brain imaging, Cognition, Hippocampal formation, Manifest arterial disease

Outcome measures

Primary outcome

Outcome variables for the primary objective are 1a) hippocampal and entorhinal cortex volume at 1.5T MRI, and 1b) cognitive functioning and late-life depression after 7 years of follow-up.

Outcome variables for the second objective are 2a) cognitive functioning and late-life depression, and 2b) volumes of hippocampal subfields at 7T MRI.

Secondary outcome

Not applicable.

Study description

Background summary

At older age, depression and cognitive decline are very common, and often co-occur. However, the nature of the relation between late-life depression and cognitive decline is not well understood. Vascular brain changes and atrophy of the hippocampal formation are associated with both depression and cognitive decline, but they are also commonly observed in normal aging, and are thus relatively aspecific neurobiological markers for depression and cognitive decline. At conventional (1.5T- 3T) MRI it is possible to differentiate the entorhinal cortex from the rest of the hippocampus, and studies indicate that the entorhinal cortex is affected in an earlier stage of cognitive decline / Alzheimer*s disease than the rest of the hippocampus. We hypothesize that the entorhinal cortex and the rest of the hippocampus differentially increase risk

for cognitive decline and late-life depression, and that they are differentially related to risk factors.
Recently, we made it possible for the first time to visualize and measure the other subfields within the hippocampus using ultra high field strength (7T) MRI. We hypothesize that these subfields also are differentially related to risk factors, cognitive decline and late-life depression.

Study objective

The first (primary) objective (study 1) is to examine 1a) risk factors for volume loss in the entorhinal cortex and compare these with risk factors for volume loss in the rest of the hippocampus at 1.5T MRI over 7 years of follow-up; and to examine 1b) whether the entorhinal cortex and the rest of the hippocampus differentially increase risk for cognitive decline and late-life depression over 7 years of follow-up in patients with manifest arterial disease.

The second objective (study 2) is 2a) to examine whether subfields of the hippocampal formation at 7T MRI are differentially related to cognitive impairment and late-life depression; and 2b) to explore risk factors of subfield volume reductions in patients with manifest arterial disease.

Study design

The study design of the primary objective is a prospective cohort study; for the second objective the design is a cross-sectional study.

Study burden and risks

The burden will consist of a visit to the UMC Utrecht on a normal weekday, which will take about the whole day and completing an extra questionnaire at home. Upon suspicion of pregnancy, a pregnancy test will be performed before the 7T MRI can take place.
The risks will be the possibility of nausea or dizziness during the MRI. These risks will not result in permanent damage, but only in short-term discomfort.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

All persons still alive who participated in the baseline examination of the SMART-Medea study from 2006 through 2009.

Exclusion criteria

Contra-indications for MR imaging (metal objects in the body, claustrophobia, pregnancy). Terminally ill or physically unable to come to the UMCU.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-12-2013
Enrollment:	420
Type:	Actual

Ethics review

Approved WMO Date:	11-03-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	10-02-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	15-04-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	27-10-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL38085.041.12