Sleep and cognition hypothesis in maritime pilots

Published: 01-09-2016
Last updated: 20-04-2024

Relationship between chronic sleep deprivation and AD

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON47817

Source
ToetsingOnline

Brief title
SCHIP

Condition

- Other condition

Synonym
Alzheimer's disease, dementia

Health condition

Neurodegeneratieve ziekten

Research involving
Human

Sponsors and support

Primary sponsor: Geriatrie
Source(s) of monetary or material Support: Ministerie van OC&W,Internationale Stichting Alzheimer Onderzoek (ISAO)

Intervention

Keyword: Alzheimer's disease, chronic sleep deprivation, cognition, sleep

Outcome measures

Primary outcome

Amount of SWS during one night of polysomnography, total score on cognitive testing

Secondary outcome

- Difference in duration of SWS between maritime pilots and controls (PSG);
- Brain amyloid load in maritime pilots (compared to normative population-based values);
- Cortical and hippocampal atrophy in maritime pilots;
- DMN activity in maritime pilots;
- Cognitive effort trade-off in maritime pilots;
- Functional and structural connectivity in maritime pilots;
- Presence of small vessel disease (SVD) in maritime pilots;
- Cerebral blood flow in maritime pilots.

Study description

Background summary

Recent evidence shows a bi-directional relationship between poor sleep and Alzheimer*s disease (AD). Sleep disorders are more frequent and severe in AD patients compared to normal aging, and in turn, poor sleep seems to have a causal role in the pathology of AD by influencing the clearance and production of the amyloid beta protein. However, the effect of chronic sleep deprivation on cognitive decline and AD has not been investigated. To demonstrate the effect of chronic sleep deprivation for over a period of time, we will perform

a controlled trial in a group that has an extrinsic cause of their poor sleep.

Study objective

Relationship between chronic sleep deprivation and AD

Study design

An observational case-control study in male Dutch maritime pilots, aged 55-60 (n=20) and age-matched volunteers (n=20). Both groups will first wear an actiwatch for 2 weeks. Participants will then have one night of polysomnography with neuropsychological testing the following morning. In the next phase, the maritime pilots will undergo PET-CT and MRI scans, on separate measurement days. In the two weeks preceding these scans, the maritime pilots will use the wearable SmartSleep device during their sleep to measure the duration and quality of sleep.

Study burden and risks

De proefpersonen zullen in totaal 4 bezoeken hebben, waarin wordt verwacht dat zij tijdens het tweede bezoek een nacht polysomnografie hebben op locatie. Wij verwachten een minimaal risico voor onze proefpersonen, de stralingsbelasting van de PET-CT is gering. Er kan irritatie zijn door het langdurig dragen van het actiwatch horloge of het aanbrengen van de electrodes voor polysomnografie voor mensen met een gevoelige huid.

The study consists of 4 visits, with one night of polysomnography on location (visit 2). We expect minimal risks for the participants, the radiation exposure is minimal. As there is risk of accidental findings, all PET-CT and MRI will be read by a trained physician. The investigator will consult the physician of this study in case a report is made of an incidental finding, other than age-appropriate brain damage (mild general atrophy and white matter lesions). In case a clinically relevant incidental finding is made, the subject will be contacted by the physician to discuss the finding. If needed, appropriate steps are taken to handle the incidental finding (additional examinations, treatment).

Contacts

Public
Selecteer

Reinier Postlaan 4
Nijmegen 6525 GC

NL
Scientific
Selecteer

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

Maritime pilots, -Written informed consent
-Age 50-60
-Male
-Subject is in good health as established by medical history
-Medication free, Healthy volunteers

-Written informed consent
-Age 50-60
-Male
-Finished HBO education
-Subject is in good health as established by medical history
-Medication free
-Normal sleep behavior, Pittsburg Sleep Quality Index score of <5
-Sleep schedule within the range of bedtime 8PM-12AM and waketime 4AM-8AM

Exclusion criteria

-Self reported difficulty in sleeping in unfamiliar environment
-Use of sedative-hypnotic medication

-Abnormal movement of the non-dominant arm
-Inability to understand Dutch
- Subjects with contra indications for PET-CT and/or MRI, e.g. due to claustrophobia, metal in upper body, have an implant or who suffer from epilepsy.
Subjects who are currently participating in another study or have participated in a clinical study within 30 days, based on their own report about participation history
-Subjects with a history of drug or alcohol abuse
-Subjects who are part of the study staff personnel or family members of the study staff personnel
-Neurological disorder (stroke, dementia, epilepsy, brain trauma)
-Subjects who wish not to be informed of accidental findings in the PET-CT and/or MRI part of this study.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	23-11-2016
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	01-09-2016

Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Not approved Date:	30-10-2017
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	05-06-2018
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	25-03-2019
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	30-07-2019
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	15-07-2020
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	NL55712.091.16