Cognitive and emotional effects of sleep apnea and its rehabilitation in stroke patients

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Ethical review	-
Status	Will not start
Health condition type	Central nervous system vascular disorders
Study type	Interventional

Summary

ID

NL-OMON36138

Source
ToetsingOnline

Brief title
CESARS

Condition

- Central nervous system vascular disorders
- Upper respiratory tract disorders (excl infections)

Synonym
obstructive sleep apneu syndrome (OSAS); sleep disordered breathing (SBD)

Research involving
Human

Sponsors and support

Primary sponsor: Heliomare
Source(s) of monetary or material Support: Heliomare

Intervention

Keyword: cognition, CPAP, sleep apnea syndrome, stroke

Outcome measures

Primary outcome

The primary outcomes of this study are fatigue, cognitive and emotional functioning, and daily living activities (neuropsychological evaluation).

Secondary outcome

Secondary measures are sleep quality and cerebral functioning. Sociodemographic and clinical data, CPAP compliance and nocturnal arousal will also be included as control measures.

Study description

Background summary

Several studies have shown a relationship between (obstructive) sleep apnea syndrome (SAS) and cardiovascular diseases, such as hypertension, heart disease and stroke. SAS has also been associated with increase of fatigue and depression, and a decrease of cognitive functioning, more particular in the domains of attention and memory. Although research on SAS in stroke patients is scarce, it seems that SAS has an additional negative effect on existing cognitive deficits due to the stroke. Continuous positive airway pressure (CPAP) is the most frequently used treatment for SAS.
In otherwise healthy SAS patients CPAP treatment has been found to improve fatigue, cognitive functioning, mood and quality of life.

Study objective

In this study the effect of SAS and the treatment with CPAP on cognitive functioning, fatigue and mood in stroke patients will be investigated. The main research questions are: 1) Is there a relationship between (the severity of) SAS and cognitive functioning, mood, fatigue, sleep quality and cerebral functioning? 2) Does decrease of SAS by means of adequate treatment like CPAP improve cognitive functioning, mood, fatigue, sleep quality and cerebral functioning? Firstly, we expect to confirm that SAS has an additional negative

effect in stroke patients on cognitive functioning, mood, fatigue and sleep quality. Secondly, we expect that CPAP treatment will improve the sleep quality, fatigue, mood and cognitive impairments, in particular in the stroke affected domains.

Study design

3-arm, randomized, placebo-controlled crossover study

Intervention

Two weeks of nocturnal use of continuous positive airway pressure (CPAP), sham CPAP or no treatment followed by two weeks of nocturnal CPAP or no treatment.

Study burden and risks

All stroke patients admitted in Heliomare revalidatie will be screened for SAS and will undergo a neuropsychological assessment (T=0). Present day Heliomare is the only rehabilitation centre in the Netherlands that screens stroke patients as part of the usual intake procedure. Subjects with SAS will be randomized to one of three experimental conditions and subjects without SAS will be assigned to a control condition. All subjects will undergo a repeated neuropsychological assessment. Additionally, SAS patients will be asked to undergo a polygraphic sleep examination before and after the intervention periods. In a subgroup of the SAS patients (N=36) an fMRI scan will also be administered at the different time points. In the experimental condition CPAP therapy will be given. Treatment will be delayed or discontinued for two weeks or two weeks of placebo treatment will be given.

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

First-time stroke confirmed by neurological assessment and CT or MRI scan
Baseline measurement (T<=0) between 4 to 16 weeks after stroke
Able to cooperate with sleep apnea (SAS) screening and neuropsychological assessment
Informed consent for study participation
18-85 years of age
Obstructive or mixed SAS (for experimental group)

Exclusion criteria

Severe unstable medical conditions
Severe cardiac problems (like angina pectoris or pacemaker/ventricular impairments)
Severe pulmonal disease (severe dyspnea of effort or severe pulmonal emphysema)
Severe aphasia or confusion, which could strongly influence the performance on the neuropsychological assessment
Severe psychiatric or somatic comorbidity, which could strongly influence the performance on the neuropsychological assessment
Central SAS only

Study design

Design

Study type: Interventional

Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Start date (anticipated):	01-06-2011
Enrollment:	120
Type:	Anticipated

Medical products/devices used

Generic name:	continuous positive airway pressure (CPAP)
Registration:	Yes - CE intended use

Ethics review

Not available

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	NL36172.018.11