Treatment of obstructive sleep apnea and rehabilitation outcome in stroke

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Central nervous system vascular disorders
Study type	Interventional

Summary

ID

NL-OMON36215

Source
ToetsingOnline

Brief title
TOROS

Condition

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

Synonym
obstructive sleep apnea syndrome (OSAS); sleep disordered breathing (SDB)

Research involving
Human

Sponsors and support

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

Intervention

Keyword: CPAP, obstructive sleep apnea syndrome, rehabilitation, stroke

Outcome measures

Primary outcome

The primary study parameters are cognitive and functional outcome.

Secondary outcome

Secondary measures are fatigue, mood and sleep quality. Sociodemographic and

clinical data, CPAP compliance, nocturnal arousal and rehabilitation therapy

will be included as control measures.

Study description

Background summary

Several studies have shown a relationship between obstructive sleep apnea syndrome (OSAS) and cardiovascular diseases, such as hypertension, heart disease and stroke. OSAS has also been associated with an increase of fatigue and depression, and a decrease of cognitive functioning. Stroke patients with OSAS have found to be more functionally impaired than stroke patients without OSAS. Moreover, OSAS seems to have an additional negative effect on existing cognitive deficits due to the stroke. Continuous positive airway pressure (CPAP) is the most frequently used method of treatment for OSAS. Although research on CPAP treatment in stroke patients is still scarce, treatment seems to improve rehabilitation outcome of stroke patients.

Study objective

In this study the relation of OSAS with functional status and cognition, and the effect of treatment with CPAP on outcomes of rehabilitation in stroke patients will be investigated. The main research questions are:
1) Is there a relationship between (the severity of) OSAS and cognitive and functional status?
2) Does CPAP treatment improve cognitive and functional outcome of rehabilitation?
Firstly, we expect to confirm that OSAS has an additional negative effect in stroke patients on cognitive and functional status. Secondly, we expect that

CPAP treatment will improve outcomes of rehabilitation in stroke patients.

Study design

Case-control study to address research question 1.
Randomized controlled trial to address research question 2.

Intervention

Stroke patients who screen positive for OSAS will be randomized over four weeks of nocturnal use of CPAP and four weeks of CAP treatment dealy (N=70). These patient groups will be compared at baseline, and after four weeks and three months (RCT part of the project), and they will be compared to patients who screen negative for OSAS (N=70; case-control part of the project).

Study burden and risks

All stroke patients admitted in Heliomare are screened for OSAS and undergo a neuropsychological assessment and assessment of functional status as part of the routine intake procedure. Present day Heliomare is the only rehabilitation centre in the Netherlands that screens stroke patients for SAS; neuropsychological evaluation is required by national guidelines for stroke rehabilitation. Subjects with OSAS will be randomized to the experimental or control condition and subjects without OSAS will be assigned to an observational control group. All subjects will undergo two more cognitive and functional assessments after the treatment period and at follow-up after two months. Additionally, OSAS patients will be asked to undergo a polygraphic sleep examination after the intervention period and at follow-up. In the experimental condition four weeks of CPAP therapy will be given, while in the control condition CPAP treatment is delayed for four weeks.
There is no risk associated with participation in this study.

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-scan or MRI-scan
Baseline measurement (T<=0) between 1 to 16 weeks after stroke
Able to cooperate with SAS screening and neuropsychological assessment
Informed consent for study participation
18-85 years of age
Obstructive or mixed SAS (for intervention part of the study)

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
Severe OSAS (AHI>60 in combination with desaturations below 70%), which could endanger patient's health if CPAP treatment is not immediately started
Obesity hypoventilation syndrome

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-10-2011
Enrollment:	140
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 20314
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL37330.018.11
OMON	NL-OMON20314