

Treatment of obstructive sleep apnea and rehabilitation outcome in stroke.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20314

Source

Nationaal Trial Register

Brief title

TOROS

Health condition

sleep apnea
OSAS
stroke
CPAP
rehabilitation

Sponsors and support

Primary sponsor: Heliomare Research and Development
Heliomare R&D
Relweg 51, 1949 EC Wijk aan Zee
Postbus 78, 1940 AB Beverwijk

University of Amsterdam

Source(s) of monetary or material Support: Heliomare R&D

Intervention

Outcome measures

Primary outcome

1. Neuropsychological assessment;
2. functional assessment.

Secondary outcome

1. Sleep quality (actigraph);
2. Fatigue (CIS-20r);
3. Mood (HADS).

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 is found to improve rehabilitation outcome of stroke patients.

In this study the relationship of OSAS with cognitive and functional status, and the effect of treatment with CPAP on outcomes of rehabilitation in stroke patients will be investigated.

Study objective

In this study the relationship of OSAS with cognitive and functional status, 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

4 weeks and 3 months.

Intervention

CPAP treatment. Patients will be randomized between two groups:

1. Patients receive CPAP directly;
2. Patients will receive CPAP after 4 weeks.

Contacts

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Eligibility criteria

Inclusion criteria

1. Stroke confirmed by neurological assessment and CT-scan or MRI-scan;
2. Baseline measurement (T=0) between 1 to 16 weeks after stroke;
3. Able to cooperate with SAS screening and neuropsychological assessment;
4. Informed consent for study participation;
5. 18-85 years of age;
6. Obstructive or mixed SAS (for intervention part of the study).

Exclusion criteria

1. Severe unstable medical conditions;
2. Severe cardiac problems (like angina pectoris or pacemaker/ventricular impairments);
3. Severe pulmonary disease (severe dyspnea of effort or severe pulmonary emphysema);
4. Severe aphasia or confusion, which could strongly influence the performance on the neuropsychological assessment;
5. Severe psychiatric or somatic comorbidity, which could strongly influence the performance on the neuropsychological assessment;
6. Central SAS only;
7. Obesity hypoventilation syndrome;
8. Severe OSAS (AHI > 60 in combination with desaturations below 70%), which could endanger patient's health if treatment is not immediately started.

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	05-10-2011
Enrollment:	70
Type:	Anticipated

Ethics review

Positive opinion	
Date:	26-04-2012
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 36215
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3259
NTR-old	NTR3412
CCMO	NL37330.018.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Register

OMON

ID

NL-OMON36215

Study results

Summary results

N/A