Treatment of obstructive sleep apnea and rehabilitation outcome in stroke.

Gepubliceerd: 26-04-2012 Laatst bijgewerkt: 19-03-2025

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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20314

Bron
Nationaal Trial Register

Verkorte titel
TOROS

Aandoening

sleep apnea
OSAS
stroke
CPAP
rehabilitation

Ondersteuning

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

University of Amsterdam
Overige ondersteuning: Heliomare R&D

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Neuropsychological assessment;
2. functional assessment.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

4 weeks and 3 months.

Onderzoeksproduct en/of interventie

CPAP treatment. Patients will be randomized between two groups:

1. Patients receive CPAP directly;

2. Patients will receive CPAP after 4 weeks.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel

Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	05-10-2011
Aantal proefpersonen:	70
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	26-04-2012
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 36215
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3259
NTR-old	NTR3412
CCMO	NL37330.018.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON36215

Resultaten

Samenvatting resultaten
N/A