The feasibility of continuous positive airway pressure ventilation in acute ischemic stroke patients: a pilot study

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The aim of this pilot study is to assess the feasibility of the use of CPAP in the acute phase of stroke in AIS patients. In other words, we want to evaluate if the treatment is tolerated and whether it can be applied as scheduled.

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

Summary

ID

NL-OMON48215

Source
ToetsingOnline

Brief title
The feasibility of CPAP in acute ischemic stroke patients - a pilot study

Condition

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

Synonym
cerebral infarction, ischemic stroke

Research involving
Human

Sponsors and support

Primary sponsor: OLVG
Source(s) of monetary or material Support: ZonMw-subsidie

Intervention

Keyword: acute ischemic stroke, continuous positive airway pressure, obstructive sleep apnea

Outcome measures

Primary outcome

The primary endpoint is feasibility defined as CPAP compliance during the

study period. Compliance is expressed as the average use of CPAP per night

measured by a memory card integrated in the CPAP device. Good compliance will

be defined as an average usage of more than 4 hoursper night.

Secondary outcome

Secondary endpoints:

- Inclusion rate

- Adverse events (AE): CPAP related AEs

- Percentage of withdrawal from CPAP treatment

- Self-evaluation of CPAP by patients and their caregivers

- Functional status: The National Institutes of Health Stroke Scale (NIHSS) and

modified Rankin Scale (mRS)

- Cognitive status: Montreal Cognitive Assessment (MoCA) and Trail Making Test

(TMT)

- OSA prevalence measured by polysomnography (PSG)

- Epworth Sleepiness Scale (ESS)

Study description

Background summary

The prevalence of obstructive sleep apnea (OSA) in stroke patients is high and evidence shows that OSA is negatively correlated to cognitive and functional recovery in ischemic stroke (IS) patients. Previous studies suggest that initiation of continuous positive airway pressure (CPAP) gives a greater improvement in cognitive status and acceleration of neurological recovery in IS patients diagnosed with OSA. However, currently OSAS in stroke patients is often left untreated or undiagnosed and to the best of our knowledge, no studies have been performed analysing the effect of CPAP in, first-ever, acute IS (AIS) patients in the very acute phase. Although previous studies suggest the beneficial effect of this treatment in stroke recovery, compliance issues seem to be greater in AIS patients. This is probably because of the variety of symptoms related to AIS, such as aphasia and/or a decrease in awareness, which makes proper verbal instructions difficult. In addition, One could also argue that masks problems may be greater than in OSA patients, since AIS patients occasionally suffer from (partial) facial and pharyngeal palsy and as a consequence might experience fitting problems and leakage of their CPAP mask. Furthermore, since CPAP treatment in this specific patient group is not part of regular treatment guidelines this may lead to logistics problems in therapy support, resulting in low compliance.

Study objective

The aim of this pilot study is to assess the feasibility of the use of CPAP in the acute phase of stroke in AIS patients. In other words, we want to evaluate if the treatment is tolerated and whether it can be applied as scheduled.

Study design

We will perform a pilot study with a follow-up period of 3 months per patient. Ten consecutive patients who give informed consent admitted to the stroke unit with an AIS will receive CPAP. Patients will receive CPAP within 24 hours after hospital admission, but at least 3 hours after alteplase infusion, during the total study period of 3 months during sleep. Patients will be admitted to the stroke unit for 24 hours and subsequently transferred to the Neurology unit. During admission, patients and their caregivers (e.g. family, friends) will receive verbal and written instructions on how to use the device. After hospital discharge, a specialized nurse will provide therapy support, in patients* home situation or rehabilitation center, to evaluate therapy compliance and to determine whether there are any other therapy-related problems. This consists of a weekly consultation by phone and visit to home or rehabilitation center if indicated. After 3 months of follow-up a PSG will be performed in combination with a follow-up visit at the Neurology department. A wash-out period of one week for CPAP will be applied to prevent the possible influence CPAP on PSG results.

Intervention

In 1981, CPAP was introduced for the treatment of patients with OSA. Since then, CPAP is considered the gold standard treatment in patients with moderate to severe OSA. CPAP acts as a pneumatic splint, preventing the upper airway from collapsing. Although, the therapy is hampered by a high level of non-compliance- 1 out of 3 patients does not tolerate CPAP-, the efficiency when used is high. Successful treatment is defined when AHI is reduced to less than 5.

Possible side effects can be related to the interface (skin abrasion from contact with the mask, claustrophobia, mask leak, irritated eyes), pressure (nasal congestion and rhinorrhea with dryness or irritation of the nasal and pharyngeal membranes, sneezing, gastric and bowel distension, recurrent ear and sinus infections) and negative social factors.

Study burden and risks

CPAP is generally accepted as a safe and effective treatment of moderate to severe OSA patients and the risks are limited.

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

* 18 years and older
* First-ever AIS (onset < 4.5hours)

Exclusion criteria

* Medical history of IS
* Medical history of OSA
* Hemorrhagic stroke
* TIA

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-09-2019
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	Continious positive airway pressure

Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	09-05-2019
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	01-07-2019
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL69474.100.19