Sleep apnea and disorders in cognitive and emotional functioning after stroke

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Determination of SDB prevalence in patients after strokeDetermination of the relationships between SDB (in particular OSAS) and complants of fatigue and complaints of emotional and cognitive disturbances in patients who experienced a stroke....

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Sleep disturbances (incl subtypes)
Study type	Observational non invasive

Summary

ID

NL-OMON34248

Source
ToetsingOnline

Brief title
Sleep apnea after stroke

Condition

- Sleep disturbances (incl subtypes)

Synonym
apnea, obstructive sleepapnea, sleep disorderd breathing

Research involving
Human

Sponsors and support

Primary sponsor: Sint Elisabeth Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cognitive, OSAS, SDB, Stroke

Outcome measures

Primary outcome

Primairy study parameters: prevalence of SDB (particularly OSAS) 3 months

after stroke

Value of polygraphy in a selected group of patients (3 months after a stroke)

Secondary outcome

Secundairy study parameters:Sleep disordered breathing, in particular

obstructive sleepapnea and subjective and objective cognitive disorders

Study description

Background summary

1. Background

1.1 Sleep apnea and stroke

Sleep apnea is a common condition in patients who have experienced a stroke. It is the most common form of sleep disordered breathing (SDB), a disorder with an inefficient respiration during sleep, which is often neglected after stroke.
The reported prevalence of SDB following stroke varies from 44% to 72%. In a recent review, the reported prevalence of SDB after stroke was 50-70%. In most studies no relationship was found between SDB and stroke severity, topography and the presumed etiology. SDB was found more often in recurrent stroke, than first-ever stroke, and the frequency was similar after TIA and stroke. This suggests that in many cases SDB is a preexistent condition. Several studies have shown that is SDB predisposes to cardiovascular diseases.

The most common form of SDB is obstructive sleep apnea syndrome (OSAS, which is characterized by repeated high airway obstructions during sleep, with desaturations and arousals, leading to less efficient sleep, less deep and less REM sleep. Patients often experience severe fatigue during the day. In patients who have experienced a stroke, obstructive apneas (OSA), but also central

apneas (CSA) and Cheyne-Stokes breathing (CSB) are seen regularly, particularly in the acute phase after stroke. CSA/CSB often improves in the subacute phase, which suggest that breathing abnormalities are exacerbated bij stroke. However, 2 to 3 months after the acute stroke approximately 50% of patients still meet the criteria of OSAS.

1.2 Sleep disordered breathing, definitions and diagnostics

For the definition of SDB, in particular OSAS, recommendations of the AASM (American Academy of Sleep Medicine), published in 1999, are used worldwide. In the Netherlands, these recommendations were published in the CBO guidelines "Diagnostics and treatment of the obstructive sleep apnea for adults" in 2009

Screening for SDB may be warranted in all stroke patients who may potentially accept CPAP treatment. SDB can be accurately diagnosed by respiratory polygraphy, in which nasal airflow, respiratory movements, and capillary oxygen saturation are monitored. Polysomnography offers additional information, but is expensive and less commonly available. It should therefore be reserved for unclear cases.
A polysomnography is a polygraphy with at least EEC (electroencephalografy), electro-oculography (EOG) and EMG (registration electromyography).

1.3 Sleep disordered breathing (SDB), fatigue and complaints of cognitive and emotional functioning

In the literature links are found between SDB and concentration disorders, fatigue, memory disorders, depression and anxiety.
Excessive daytime sleepiness (EDS) and fatigue are associated with neuropsychiatric (depression, anxiety) and cognitive disorders and have a negative impact on rehabilitation and quality of life.

1.4 Stroke, fatigue and complaints in cognitive and emotional functioning

In patients who have experienced a stroke, disorders in emotional and cognitive function are frequently seen. Hypersomnia, EDS (excessive daytime sleepiness) and fatigue after a stroke was frequently seen in a recent study, as was insomnia.

It is not yet entirely clear to what extent SDB is responsible for, or contributes to the frequent reported emotional disorders and cognitive function.

1.5 COMPAS study: objective and subjective cognitive complaints after stroke
In 2007 and 2008, M. van Rijsbergen, neuropsychologist and researcher at the University of Tilburg, conducted a study in the context of her Master Thesis Medical Psychology, on the relationship between subjective and objective memory complaints in patients after a stroke in the St. Elisabeth and TweeSteden

Hospital. This study showed a consistent association between subjective memory complaints and cognitive limitations, such as fatigue, anxiety and depression in patients after stroke with a follow up of 6 months. 31

As part of her promotion research: The COMPAS study (COgnitive coMPlaints After Stroke), (promoter Prof. Dr. M. Sitskoorn, co-promoters Dr. R. Mark, Dr. P.L.M. de Kort), she will carry out a follow-up study in patients after stroke, which started March 2010. In this study subjective complaints regarding cognitive and emotional functioning are examined in relation to objective disorders in cognition, emotion and psychiatric disorders.

1.6 Substudy in COMPAS: Relation between sleep disordered breathing (in particular OSAS) and complaints of fatigue and emotional and behavioural problems after a stroke.

Considering the frequency of sleepapnea in patients after stroke, the association of sleepapnea with complaints of fatigue and cognitive disturbances and the frequency of fatigue and cognitive impairment after stroke, it is likely that there are links between sleepapnea and cognitive complaints after stroke. A study with attention to the patients complaints has not yet been conducted.

1.7 Conclusion and relevance

Sleep disordered breathing (SDB), in particular OSAS, is a common disease in patients who have experienced a stroke. In addition, SDB is a risc factor for stroke recurrence and other heart and vascular diseases. It is a well-known fact that SDB results in fatigue and concentration disorders, disorders of the cognitive and emotional functioning. In patients who have experienced a stroke, disorders in emotional and cognitive function are frequently seen. It is not yet entirely clear to what extent SDB is responsible for or contributes to the frequent reported emotional and cognitive disorders after stroke.

Research in this area is of great social importance. 41 000 new patients suffer from stroke each year in the Netherlands (ref NHS). The number of patients will only rise, by ageing of the population in the future. Stroke is the main cause of chronic disability in adulthood, is related to a lower quality of life and is responsible for a great deal of docter*s consultation. SDB, in particular OSAS, is seen in 50% of stroke patients in the subacute phase and is a risc factor for stroke recurrence. Worldwide no standard screening is performed for SDB after stroke. Many patients experience fatigue and cognitive disturbances after stroke. Patients with SDB also experience this. It seems likely that there*s a relationship between subjective cognitive complaints, objective cognitive and emotional disorders and SDB in patients after stroke. This study can provide more insight on this relationship en could be a start for better treatment for patients after stroke.

1.8 Hypothesis

In patiënts who have experienced a stoke, there is a high prevelance of SDB (in particular OSAS)

There is a relationship between SDB (in particular OSAS) and complaints of fatigue and complaints of emotional and cognitive disturbances in patients who have recently experienced a stroke.

There is a relationship between SDB (in particular OSAS) and objective cognitive disorders in patients after stroke

Sleep disordered breathing (in particular OSAS) plays an important role in fatigue complaints after a stroke.

In the subacute phase of a stroke (after 2-3 months) a portable (type 4) polygraphy is a good screening instrument for sleepapnea.

Study objective

Determination of SDB prevalence in patients after stroke

Determination of the relationships between SDB (in particular OSAS) and complants of fatigue and complaints of emotional and cognitive disturbances in patients who experienced a stroke.

Determination of the relationships between SDB (in particular OSAS) and objective cognitive disorders in patients after stroke

To use a simple, portable type 4 polygraphy monitoring as a screeninginstrument for SDB in the subacute phase of stroke, compared to the golden standard polysomnography

Study design

This study is partly a substudy in the COMPAS study, in which patients are followed up 2 years after their stroke. Current study will confine itself to the first moment of inclusion in the COMPAS study, that is to say, three months after the occurrence of the stroke.
During their regular visit to the outpatient clinic, these patients are asked to answer a questionnaire on sleep, and a diagnostic ambulant polygraphy will be carried out.
In case the polygraphy shows evidence of SDB, patients will be referred to a neurologist with specialisation in sleepdisorders and a polysomnography (PSG) will be ordered. If a patient is found to have OSAS, regular treatment will be facilitated. Performing PSG and treatment are beyond the scope of this

research.
Current research can therefore be seen as a correlation study, in which the correlation between SDB and cognitive and emotional disorders are measured in patients who have experienced a recent stroke.

In addition, all patients who have experienced a stroke (including those who won't participate in the COMPAS study) will be given a one-night type 4 portable polygraphy monitoring during their admission on the stroke care unit. Patients who don't participate in the COMPAS study will also be asked to fill in a questionnaire on sleep during their oupatient clinic visit, and will be asked to participate in current study to perform an ambulant polygraphy monitoring.
This way prevalence of SDB during acute and subacute phases of stroke can be measured, and polygraphy type 4 monitoring can be compared to golden standard polysomnography.

Study burden and risks

During the admission on the stroke care unit patients will be asked to answer a 10-point questionnaire and a 1-night registration with the Apneulink polygraphy (type 4 polygraphy monitoring) is registred. During their planed, regular visit at the outpatient clinic, 6 weeks after discharge, patients will be asked to participate in current study. A second questionnaire on sleep will be given to the patients to be answered at home. A second registration with the type 4 portable ambulant polygraphy will be performed. Patients can apply the monitor easily themselves at home. After a one-night registration they can return the device to the hospital. If, on basis of the questionnaire and/or the polygraphy monitoring, there is a reasonable suspicion on SDB, patients will be referred to a neurologist with experience in sleepmedicine. Polysomnography and treatment will be performed following regular diagnostic en treatment guidelines and is beyond the scope of this study.

Participation in this study is non-invasive, save and without specific risks.
In case the results of the questionnaire and/or the polygraphy give resons for concerns, patients are referred to their treating physician (after consent).
Furthermore, all patients who are suspected of SDB on basis of the polygraphy measurement are referred to a neurogist with experience in sleepmedicine for further diagnostic procedures and possible treatment.

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

Clinical diagnosis of cerebral vascular incident, first ever or recurent stroke
Age >= 18
Aphasia
reduced consciousness

Exclusion criteria

Diagnosis of SAH (subarachnoidal hemmorhage);Premorbid dependency (modified Rankin Scale>4)

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2010
Enrollment:	500
Type:	Actual

Ethics review

Approved WMO

Date:	14-06-2010
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

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	NL32004.008.10