The effectiveness of CPAP-therapy on recurrence of atrial fibrillation after cardioversion in patients with central sleepapnea

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The objective of this study is evaluation of the effectiveness of CPAP-therapy on recurrence of atrial fibrillation after cardioversion in patients with central sleepapnea and in case of proven effectiveness possibly using CPAP-therapy as standard...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Cardiac arrhythmias
Study type	Observational non invasive

Summary

ID

NL-OMON41889

Source
ToetsingOnline

Brief title
CPAPAFCSA

Condition

- Cardiac arrhythmias
- Sleep disturbances (incl subtypes)

Synonym
arrhythmia, central sleepapnea

Research involving
Human

Sponsors and support

Primary sponsor: Orbis Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: atrial fibrillation, cardioversion, central sleepapnea, CPAP

Outcome measures

Primary outcome

Recurrence of atrial fibrillation under CPAP-therapy

Secondary outcome

Presence of additional secundary parameters (bloodpressure, diabetes, age)

Study description

Background summary

In sleepapnea (SA) the sleep is disturbed bij impaired breathing during nightsleep. Within this impaired breathing it is possible to see apneas (stopped breathing) as well as hypopneas (reduced breathing). Sleepapnea is differentiated in obstructive (OSA) and central sleepapneas (CSA). OSA is a result of collaps of the upper airway due to sleep related muscle relaxation, The upper airway collaps can be caused bij muscle relaxation in aging, obesity or anatomical problems such as loose palate, polyps or a too large tongue. This is characterised by an apnea during a minimum of 10 seconds with thorax expansion. CSA is caused by a disturbed cerebral regulation of respiration. This is characterised by an apnea during a minimum of 10 seconds without thorax expansion.
These rules, recorded bij the American Academy of Sleep Medicine (AASM), are importent when analyzing the polysomnography (PSG). A PSG is a sleeptest where an number of topics are registered, such as brainactivity, respiration, blood-oxygenlevels and heartfrequency.
The severeness of SA is determined according to the apnea-hypopnea-index (AHI), calculated by hour, determined during PSG. AHI < 5/hour is normal.
The diagnosis sleepapnea is made at a AHI above five times an hour. The mixed form, central combined with obstructive, is frequently seen. The treatment for OSAS consists of conservative treatment like changes in lifestyle in obesity (motion, healthy weight, healthy nutrition) and/or surgical treatment like

enlarging the space in oral cavity and pharynx. In addition it is possible to treat with continuous positive airway pressure (CPAP), where patients sleep with a mask over their nose and mouth which is connected to a machine that supports every inhalation with enough overpressure to abolish the apnea. Because CSA is caused by disturbed cerebral regulation of respiration, conservative treatment doesn*t work and CPAP is used as treatment. The CPAP-mechanism in CSA is based on using overpressure to create good ventilation and diffusion of oxygen to the bloodstream and carbonic back to exhalation. Then chemoreceptors in the body use this balance of oxygen and carbonics in the bloodstream to encourage the brain to respiratory stimulus.
Patients with heart and vascular disease have increased incidence to develop CSA and vice versa. CSA gives aggravation of heartfailure due to exposure of the heart to variable oxygen supply, increased burden on the heart, activation of sympathic nervous system and damage to endothelial tissue. Literature says there is a strong association between sleeapnea and atrial fibrillation (AF), a arrhythmia from the atria of the heart. The prevalence of AF is higher in CSA-patients than it is in OSA-patients. AF can be treated with anti-arrhytmic medication or cardioversion. The medication attempts to restore and sustain normal rhytm (sinusrhytm). If this is not sufficient a cardioversion is considered. Cardioversion is a non-invasive intervention. The patient, under light narcosis, is given an electric shock aiming to restore sinusrythm. AF can recur after treatment. This possible shortly after the treatment or at a later date.

Study objective

The objective of this study is evaluation of the effectiveness of CPAP-therapy on recurrence of atrial fibrillation after cardioversion in patients with central sleepapnea and in case of proven effectiveness possibly using CPAP-therapy as standard treatment.

Study design

Pilotstudy, randomized clinical trial (RCT)

Study burden and risks

No risks, burden of a checklist, an intake, polysomnography and 3 follow-up appointments.

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

Central or combined central/obstructive sleepapnea with central apnea/hypo-apnea index above 5 times/hour
atrialfibrillation

Exclusion criteria

heartfailure
other heartrythmdisorders
purely obstructive sleepapnea
treatment with CPAP-therapy

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	30
Type:	Anticipated

Medical products/devices used

Generic name:	CPAP-therapy
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	04-03-2015
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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	NL51056.096.14