

Impact of standard continuous positive airway pressure (CPAP) therapy on arterial hypertension in patients with obstructive sleep apnoea syndrome (OSAS)

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Registration date 20/04/2009	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 20/04/2009	Condition category Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Ingo Fietze

Contact details
Charité - Universitätsmedizin Berlin
Charitéplatz 1
Berlin
Germany
10117

Additional identifiers

Protocol serial number
01/20-02-2008

Study information

Scientific Title

Impact of standard continuous positive airway pressure (CPAP) therapy on arterial hypertension in patients with obstructive sleep apnoea syndrome (OSAS): a prospective randomised interventional clinical trial

Acronym

CPAP and hypertension

Study objectives

The purpose of this study is to provide evidence for the impact of non-invasive positive airway pressure ventilation therapy (CPAP) on recently diagnosed and still untreated hypertension. A comparison of the 24-hour ambulatory blood pressure monitoring results of group A (subjects with obstructive sleep apnoea [OSA] and hypertension) before and 3 months after adjustment to CPAP-therapy. Simultaneously we will examine the 24-hour blood pressure results of a control group B (subjects with OSA and hypertension) which will not receive CPAP nor hypertension treatment over a period of 3 months (natural course). Diagnostics of blood pressure will be performed by 24-hour ambulatory blood pressure monitoring, sleep apnoea diagnostics will be conducted by night attended cardiorespiratory polysomnography (PSG) in the sleep lab. Adjustment to nocturnal ventilation therapy (CPAP) will also take place in sleep lab as well as the control study with (group A) and without (group B) CPAP after the 3-month period. During the first night in sleep lab (diagnostics) as well as during the control night after 3 months an additional recording of peripheral arterial tonometry (PAT) on the fingertip will be performed.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Charite - Universitaetsmedizin Berlin Ethics Committee gave approval on the 20th May 2008 (ref: EA1/044-08)

Primary study design

Interventional

Study design

Prospective randomised interventional clinical trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Obstructive sleep apnoea

Interventions

Prospective randomised interventional clinical trial including 40 patients with an OSAS which requires treatment and with recently diagnosed arterial hypertension.

Group A: patients receive CPAP treatment immediately

Group B: patients start CPAP treatment 3 months later

Routines:

1. 24-hour ambulatory blood pressure (ABP) monitoring
2. Night attended polysomnography with additional PAT on fingertip

3. Night attended polysomnography with CPAP titration (1 APAP plus 1 CPAP night)
4. Home treatment with individual CPAP-mode
5. After 3 months repetition of night attended polysomnography with additional PAT on fingertip
6. Electrocardiogram (ECG) (12-lead)
7. Pulmonary function test (spirometry)
8. Ambulatory cardiorespiratory polygraphy
9. 24-hour ambulatory blood pressure (ABP) monitoring
10. Checking for inclusion/exclusion criteria
11. Sonography of kidney arteries
12. Vanillylmandelic acid (VMA) in urine

Total duration of treatment: 12 weeks

Total duration of follow-up: 12 weeks

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Arterial blood pressure with and without CPAP-therapy over the course of 3 months

Key secondary outcome(s)

1. Cardiac output (left ventricular ejection fraction [LVEF])
2. Nocturnal PAT
3. Quality of sleep
4. Quality of life (QoL)
5. Day sleepiness (Epworth Sleepiness Scale [ESS] score)

Measured before randomisation, first therapy night (day one of the study), and after 12 weeks.

Completion date

31/12/2010

Eligibility

Key inclusion criteria

1. Apnoea Hypopnoea Index (AHI) greater than or equal to 15/h
2. Aged greater than 18 years, either sex
3. Patient's signature on informed consent after receiving oral and written information about the study
4. Levels of hypertension 1 - 3 and isolated systolic hypertension

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. History with hypertensive crisis, known cardiac risks (coronary heart disease [CHD], heart failure, cardiac arrhythmia, congenital heart diseases)
2. Level 3 hypertension, unless patient refuses pharmacological treatment
3. Medication or drug abuse
4. Ongoing hypertension medication
5. Intake of any medication affecting sleep (e.g., medication affecting the central nervous system, tranquilisers)
6. Alcohol abuse with a daily consumption of greater than 30 g on a regularly basis
7. Participation in a pharmacological clinical trial within 4 weeks prior to enrolment to this study
8. Normal blood pressure recordings in ambulatory blood pressure monitoring (ABPM)
9. Any psychiatric or neurological sickness which could influence sleep or therapy compliance
10. Dysfunction of thyroid gland
11. Chronic pain symptoms of any origin
12. Acute cardiac, pulmonary or other internal organ diseases
13. Chronic cardiac, pulmonary or other internal organ diseases that could influence sleep
14. Existing central sleep-related breathing disorder
15. Restless legs syndrome (RLS) and/or periodic leg movement syndrome (PLMS); (Periodic Limb Movement Index [PLMI] greater than 10/h)
16. Apoplex and/or myocardial infarction history
17. Diabetes mellitus

Date of first enrolment

23/02/2009

Date of final enrolment

31/12/2010

Locations**Countries of recruitment**

Germany

Study participating centre

Charité - Universitätsmedizin Berlin

Berlin

Germany

10117

Sponsor information

Organisation

Charité - University Medicine Berlin (Charité - Universitätsmedizin Berlin) (Germany)

ROR

<https://ror.org/001w7jn25>

Funder(s)

Funder type

Industry

Funder Name

Respironics, Inc. (USA)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration