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

Submission date	Recruitment status	Prospectively registered
20/02/2009	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
20/04/2009	Completed	Results
Last Edited	Condition category	Individual participant data
20/04/2009	Nervous System Diseases	Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

01/20-02-2008

Study information

Scientific Title

Impact of standard continous 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)

Study design

Prospective randomised interventional clinical trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 measure

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

Secondary outcome measures

- 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.

Overall study start date

23/02/2009

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 sytolic hypertension

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

40

Key exclusion criteria

- 1. History with hypertentious 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 pharmalogical 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 sydrome (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

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)

Sponsor details

c/o Ingo Fietze Charitéplatz 1 Berlin Germany 10117

Sponsor type

Hospital/treatment centre

Website

http://www.charite.de/

ROR

https://ror.org/001w7jn25

Funder(s)

Funder type

Industry

Funder Name

Respironics, Inc. (USA)

Results and Publications

Publication and dissemination planNot provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summaryNot provided at time of registration