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

Submission date
20/02/2009

Registration date
20/04/2009

Last Edited
20/04/2009

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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

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)

Sponsor details
c/o Ingo Fietze
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Berlin
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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 plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration