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Comparison of continuous positive airway pressure (CPAP) with SOMNOventCR® in patients with combined obstructive sleep apnoea and Cheyne-Stokes respiration

Submission date
08/01/2009

Registration date
05/02/2009

Last Edited
18/02/2019

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Nervous System Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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
NCT00811668

Secondary identifying numbers

Wi_VentCR_12/2008

Study information

Scientific Title
Comparison of treatment with continuous positive airway pressure (CPAP) and treatment with adaptive assisted ventilation (SOMNOventCR®) in patients with combined obstructive sleep apnoea and Cheyne-Stokes respiration

Study objectives
The goal of the study was to compare this new therapeutic option (SOMNOvent CR®) with the established method of continuous positive airway pressure (CPAP) in patients with combination of obstructive sleep-apnoea syndrome and Cheyne-Stokes respiration with underlying heart disease.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the University of Witten/Herdecke (Universität Witten/Herdecke e.V.), approved in May 2008 (ref: 13/2008)

Study design
Randomised controlled cross-over single-blind single-centre 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, Cheyne-Stokes respiration

Interventions
This is a cross-over study. CPAP therapy with SOMNOsoft plus® for 4 weeks versus adaptive servo-ventilation therapy with SOMNOvent CR® for 4 weeks. There is a washout period of 1 week between the treatments.

Intervention Type

Other

Phase
Phase IV

Primary outcome measure
The central AHI, assessed by polysomnography at baseline, after four weeks therapy, and (after the wash-out period) after four weeks with the other therapy (i.e. 9 weeks).

Secondary outcome measures
1. Total AHI, assessed by polysomnography at baseline, after four weeks therapy, and (after the wash-out period) after four weeks with the other therapy (i.e. 9 weeks)
2. Left ventricular ejection fraction, assessed by echocardiography at baseline, after 4 weeks therapy, and (after the wash-out period) after four weeks with the other therapy (i.e. 9 weeks)
3. Six minutes walking test at baseline, after 4 weeks therapy, and (after the wash-out period) after four weeks with the other therapy (i.e. 9 weeks)
4. Patients' questionnaire at baseline, after 4 weeks therapy, and (after the wash-out period), after four weeks with the other therapy (i.e. 9 weeks). This will include assessment of subjective satisfaction with the therapy.
5. Minimum and middle oxygen saturation, assessed by polysomnography at baseline, after four weeks therapy, and (after the wash-out period) after four weeks with the other therapy (i.e. 9 weeks)
6. Compliance, after 4 weeks therapy, and (after the wash-out period) after 4 weeks with the other therapy (i.e. 9 weeks)

Overall study start date
13/05/2008

Completion date
31/07/2009

Eligibility

Key inclusion criteria
1. Men and women greater than 18 years
2. Diagnosis of arterial hypertension, coronary heart disease or dilative cardiomyopathy
3. Combined sleep apnoea syndrome with a total value of apnoea-hypopnoea index (AHI) greater than 15 per hour and a rate up to 20% of central events or periodic breathing

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40

Key exclusion criteria
1. Heart failure New York Heart Association (NYHA) class IV
2. Myocardial infarction, unstable angina pectoris or cardiac surgery within the last three months
3. AHI less than 15 per hour
4. Obstructive breathing disturbances up to 80%
5. Pregnancy
6. Absence of declaration of consent
7. Malign diseases
8. Serious (severe) chronic oxygen-requiring pulmonary illness
9. Aged under 18 years

Date of first enrolment
13/05/2008

Date of final enrolment
31/07/2009

Locations

Countries of recruitment
Germany

Study participating centre
Institut für Pneumologie an der Universität Witten/Herdecke
Solingen
Germany
42699

Sponsor information

Organisation
Bethanien Science Institute (Wissenschaftliches Institut Bethanien e.V.) (Germany)

Sponsor details
Aufderhöher Str. 169-175
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Sponsor type
Research organisation

Website
http://www.klinik-bethanien.de/cms.cgi

ROR
https://ror.org/03ndabk35

Funder(s)

Funder type
University/education

Funder Name
University of Witten/Herdecke (Universität Witten/Herdecke) (Germany) - Institute for Pneumology (Institut für Pneumologie) (ref: Wi_VentCR_12/2008)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2014	18/02/2019	Yes	No