

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	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 05/02/2009	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 18/02/2019	Condition category Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Wolfgang Galetke

Contact details

Institut für Pneumologie an der Universität Witten/Herdecke
Aufderhöher Str. 169-175
Solingen
Germany
42699

Additional identifiers

ClinicalTrials.gov (NCT)

NCT00811668

Protocol serial number

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

Study type(s)

Treatment

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(s)

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).

Key secondary outcome(s)

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)

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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)

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

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