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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

**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 |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |