

# Continuous positive airway pressure therapy withdrawal - a model to evaluate treatment modalities for sleep apnoea

<b>Submission date</b> 13/05/2009	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 14/07/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 15/08/2011	<b>Condition category</b> 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

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### Contact details

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## Additional identifiers

### Protocol serial number

V1.1

## Study information

### Scientific Title

Continuous positive airway pressure therapy withdrawal - a model to evaluate treatment modalities for sleep apnoea: a randomised controlled trial

### **Study objectives**

Continuous positive airway pressure (CPAP) therapy withdrawal will result in gradual deterioration in daytime symptoms of obstructive sleep apnoea (OSA), sleep study parameters of OSA severity and an increase of blood pressure, endothelial dysfunction and systemic inflammation.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Local ethics committee of the University Hospital of Zurich approved on the 13th January 2009 (ref: EK-1600)

### **Study design**

Randomised controlled trial

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Obstructive sleep apnoea

### **Interventions**

Obstructive sleep apnoea patients under treatment with continuous positive airway pressure (CPAP) will be randomised to either continue with CPAP or to sham CPAP for 2 weeks. Total time of follow-up is 2 weeks.

### **Intervention Type**

Other

### **Phase**

Not Applicable

### **Primary outcome(s)**

Severity and symptoms of OSA, measured at least at baseline, after 1 week and after 2 weeks.

### **Key secondary outcome(s))**

1. Blood pressure
2. Endothelial function
3. Systemic inflammation

Measured at least at baseline, after 1 week and after 2 weeks.

### **Completion date**

31/12/2010

# Eligibility

## Key inclusion criteria

1. Objectively confirmed obstructive sleep apnoea with an original oxygen desaturation index (ODI) (greater than or equal to 4% dips) of between 10 and 50/h
2. Currently greater than 10 oxygen desaturations (greater than or equal to 4% dips) during an ambulatory nocturnal pulse oximetry performed at the end of a 4-night period without CPAP
3. Treated with CPAP for more than 12 months, minimal compliance 4 hours per night
4. Written informed consent
5. Aged 20 - 75 years (inclusive), either sex

## Participant type(s)

Patient

## Healthy volunteers allowed

No

## Age group

Adult

## Sex

All

## Key exclusion criteria

1. Previous ventilatory failure (awake resting arterial oxygen saturation less than 93% or arterial partial pressure of carbon dioxide [PCO<sub>2</sub>] greater than 6 kPa)
2. Unstable, untreated coronary or peripheral artery disease, severe arterial hypertension (greater than 180/110 mmHg)
3. Previously diagnosed with Cheyne-Stokes breathing
4. Current professional driver
5. Any sleep related accident
6. Aged less than 20 or greater than 75 years at trial entry
7. Mental or physical disability precluding informed consent or compliance with the protocol
8. Non-feasible trial follow-up (for example, distance from follow-up centre, physical inability)

## Date of first enrolment

01/07/2009

## Date of final enrolment

31/12/2010

# Locations

## Countries of recruitment

Switzerland

## Study participating centre

**Sleep Disorders Centre and Pulmonary Division**  
Zurich  
Switzerland  
8091

## Sponsor information

### Organisation

University Hospital of Zurich (Switzerland)

### ROR

<https://ror.org/01462r250>

## Funder(s)

### Funder type

Research organisation

### Funder Name

Swiss National Science Foundation (Switzerland) (ref: 32003B\_124915/1)

### Alternative Name(s)

Schweizerischer Nationalfonds, Swiss National Science Foundation, Fonds National Suisse de la Recherche Scientifique, Fondo Nazionale Svizzero per la Ricerca Scientifica, Fonds National Suisse, Fondo Nazionale Svizzero, Schweizerische Nationalfonds, The Swiss National Science Foundation (SNSF), SNF, SNSF, FNS

### Funding Body Type

Private sector organisation

### Funding Body Subtype

Trusts, charities, foundations (both public and private)

### Location

Switzerland

## Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	15/11/2011		Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes