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

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
13/05/2009	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
14/07/2009	Completed	[X] Results
Last Edited	Condition category	Individual participant data
15/08/2011	Nervous System Diseases	

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

Dr Malcolm Kohler

#### Contact details

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# Additional identifiers

**EudraCT/CTIS** number

**IRAS** number

ClinicalTrials.gov number

Secondary identifying numbers

# 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

# 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**

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 measure

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

# Secondary outcome measures

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

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

# Overall study start date

01/07/2009

# 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

#### Age group

Adult

#### Sex

Both

# Target number of participants

40

#### Key exclusion criteria

- 1. Previous ventilatory failure (awake resting arterial oxygen saturation less than 93% or arterial partial pressure of carbon dioxide [PCO2] 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)

# Sponsor details

c/o Dr Malcolm Kohler Sleep Disorders Centre and Pulmonary Division Raemistrasse 100 Zurich Switzerland 8091 Malcolm.K@bluewin.ch

# Sponsor type

Hospital/treatment centre

#### Website

http://www.unizh.ch/

#### **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, SNF, SNSF, FNS

# **Funding Body Type**

Private sector organisation

# **Funding Body Subtype**

Trusts, charities, foundations (both public and private)

#### Location

**Switzerland** 

# **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	15/11/2011		Yes	No