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

Submission date
13/05/2009

Recruitment status
No longer recruiting

Registration date
14/07/2009

Overall study status
Completed

Last Edited
15/08/2011

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

Secondary identifying numbers

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

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
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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