ISRCTN02302064 https://doi.org/10.1186/ISRCTN02302064

Copeptin, Pro-Atrial Natriuretic Peptide (Pro-ANP) and Pro-Adrenomedullin (Pro-ADM) as markers of hypoxic stress in patients with obstructive sleep apnoea syndrome (OSAS)

Submission date 16/08/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 28/10/2010	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 28/10/2010	**Condition category** Respiratory	[_] Individual participant data [_] Record updated in last year

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

170/10

Study information

Scientific Title
Copeptin, Pro-Atrial Natriuretic Peptide (Pro-ANP) and Pro-Adrenomedullin (Pro-ADM) as markers of hypoxic stress in patients with obstructive sleep apnoea syndrome (OSAS): a prospective intervention trial

Acronym
BioSAFE

Study objectives
The primary objective of this trial is to evaluate, whether copeptin, Pro-ANP and Pro-ADM might serve as a potential proxy for prognosis and therapy response in OSAS or patients with central events by reliable reflecting hypoxic stress and responding to Continuous Positive Airway Pressure (CPAP) or Bilevel Positive Airway Pressure (BiPAP) therapy respectively. Further clinical and laboratorial predictors of therapy approve and prognosis will also be evaluated.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The conjoined local ethic committee of the cantons of Basel-Stadt and Basel-Land approved on the 23rd of August 2010 (ref: EKBB 170/10)

Study design
Prospective observational longitudinal single centre study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Obstructive sleep apnoea syndrome (OSAS)

Interventions

Visit 1a: informed consent, medical history, current medical status, demographics, vital signs, height and body weight, epworth sleepiness score, SF-36, overnight pulsoxymetry
Visit 1b: venous puncture (6 and 9 am), overnight pulsoxymetry
Visit 2a (Baseline): medical history, physical examination, vital signs, venous puncture (8 and 10 pm), overnight pulsoxymetry
Visit 2b (Baseline): venous puncture (6 and 9 am), epworth sleepiness score, SF-36
Visit 3 (1 Month): current medical status, physical examination, vital signs, height and body weight, venous puncture (6 and 9 am), epworth sleepiness score, SF-36, overnight pulsoxymetry
Visit 4 (6 months): current medical status, physical examination, vital signs, height and body weight, venous puncture (6 and 9 am), epworth sleepiness score, SF-36, overnight pulsoxymetry

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Change in median circulating copeptin, Pro-ANP and Pro-ADM levels after 1 month of CPAP or BiPAP treatment

Secondary outcome measures
1. Median circulating copeptin, Pro-ANP and Pro-ADM levels before treatment and after 1 and 6 months of treatment respectively
2. Change in median circulating copeptin, Pro-ANP and Pro-ADM levels after 1 night and 6 months of CPAP treatment respectively
In a second step, endpoints will be assessed in subgroups of patients according to OSAS severity

Overall study start date
01/09/2010

Completion date
30/04/2012

Eligibility

Key inclusion criteria
1. Patients aged 18 or older
2. Patients with suspicion of obstructive sleep apnoea syndrome or central apnoea events

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
300

Key exclusion criteria
1. Mental disorder preventing appropriate judgment concerning study participation
2. Significant co morbidity resulting in reduced life expectancy (lower than 6 months)
3. Planned emigration or relocation within the country during the study period
4. Pregnancy and breast-feeding

Date of first enrolment
01/09/2010

Date of final enrolment
30/04/2012

Locations

Countries of recruitment
Switzerland

Study participating centre
Clinic of Pneumology and Respiratory Cell Research
Basel
Switzerland
4031

Sponsor information

Organisation
University Hospital Basel (Switzerland)

Sponsor details
Prof. Michael Tamm
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04k51q396

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Hospital Basel (Switzerland) - Clinic of Pneumology and Respiratory Cell Research

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