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

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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 Clinic of Pneumology and Respiratory Cell Research Petersgraben 4 Basel Switzerland 4031

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