

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

Contact name

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Contact details

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Additional identifiers

Protocol serial number

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 reliably 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 approval 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

Study type(s)

Diagnostic

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration