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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

Registration date
28/10/2010

Last Edited
28/10/2010

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Respiratory

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] 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

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 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

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes