

# 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)

<b>Submission date</b> 16/08/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 28/10/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 28/10/2010	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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 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