

Early Sleep Apnea Treatment in Stroke: A Randomized, Rater- Biinded, Clinical Trial of Adaptive Servo-Ventilation (eSATIS)

Principal Investigator:	Dr. med. Dominique Flügel
Status:	recruiting
Project Start:	2017
Project End:	approx. 2020
Trial Design/Class:	international, multicentre, randomized, rater-blinded trial Class: A (ClinO)
Number of Patient:	100 total
Centers:	2 Swiss (Bern, St. Gallen), Berlin, Grenoble
Sponsor/Partner:	Universitätsspital Bern, Prof. Dr. med. Claudio L. Bassetti
Funding:	Universitätsspital Bern, Swiss National Science Foundation and TROPOS Foundation

Summary:

The prevalence of Sleep Disordered Breathing (SDB) after acute stroke is high (over 50% of affected patients in more than 20 studies). SDB after stroke has been found to be associated with a faster progression of stroke severity, with higher blood pressure levels and longer hospitalization in the acute phase. SDB with Adaptive Servo-Ventilation (ASV) will be implemented on the first night after stroke. Qualifying patients will be enrolled to assess the effectiveness of this treatment on infarct/lesion growth.

3 groups of patients are prospectively followed over 1 year, ASV treatment starts the second night following stroke and ends 3 months later:

- sSDB ASV+: stroke patients with an AHI ≥ 30 /h randomized to ASV treatment
- sSDB ASV-: stroke patients with an AHI ≥ 30 /h randomized to no treatment
- no SDB: stroke patients with no SDB (AHI < 5 / h)

Objectives:

The primary objective is to assess whether an immediate onset of ASV treatment in stroke patients with significant SDB (sSDB, Apnea-Hypopnea-Index (AHI) ≥ 30 /h) has a favorable effect on infarct growth assessed as the difference in lesion volume before and 90 days after treatment start.

The secondary objectives of the trial are to assess whether an immediate onset of ASV treatment in stroke patients with SDB

- improves clinical outcome and is tolerated and associated with good treatment compliance
- improves short and long-term cortical reorganization
- improves cognitive outcome
- improves physiological parameters such as blood pressure, endothelial function/arterial stiffness, and coagulation and inflammation blood parameters.