Sleep SMART

Study Design

The Sleep for Stroke Management and Recovery Trial (Sleep SMART) is designed to assess whether continuous positive airway pressure (CPAP) for obstructive sleep apnea, after stroke, helps with recovery or helps prevent another stroke, ACS, or death.

Inclusion Criteria for Consent

- Age ≥18
- Ischemic stroke within the prior 7 days
- NIH Stroke Scale Score ≥1 at the time of enrollment

Exclusion Criteria for Consent

- pre-event inability to perform all of own basic ADLs
- unable to obtain informed consent from subject or legally authorized representative
- incarcerated
- known pregnancy
- current mechanical ventilation (can enroll later if this resolves within required 7-day window from stroke) or tracheostomy
- current use of positive airway pressure, or use within one month prior to stroke
- anatomical or dermatologic anomaly that makes use of CPAP interface unfeasible
- severe bullous lung disease
- history of prior spontaneous pneumothorax or current pneumothorax
- massive epistaxis or previous history of massive epistaxis
- hypotension requiring current treatment with pressors (can enroll later if this resolves within required 7-day window from stroke)
- other specific medical circumstances that conceivably, in the opinion of the site PI, could render the patient at risk of harm from use of CPAP

- cranial surgery or head trauma within the past 6 months, with known or possible CSF leak or pneumocephalus
- recent hemicraniectomy or suboccipital craniectomy (i.e. those whose bone has not yet been replaced), or any other recent bone removal procedure for relief of intracranial pressure
- current receipt of O2 supplementation >4 liters per minute
- current contact, droplet, or respiratory/airborne precautions

Criteria for Randomization

1. Nox T3-based AHI ≥10, without substantial central sleep apnea (move on to run-in night), and
2. Run-in night aCPAP use ≥4.0 hours cumulatively, and
3. Run-in night aCPAP-derived CAI <10, and
4. After run-in night, agree that they are comfortable being assigned to CPAP or no CPAP for 6 months

Local Site Contact Information

Important Contacts

For questions:

Eligibility interpretation questions: sleepsmart@umich.edu (9am - 8pm eastern, no PHI please)

Nox T3, KOEO, aCPAP technical questions: sleepsmarttechsupport@noxhealth.com (or 404-480-5149 extension 4006)

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