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.
- The study includes two trials: a prevention study (6 month outcomes) with an embedded recovery trial (3 month outcomes).

Inclusion Criteria for Consent

- Age ≥18.
- TIA with ABCD2 ≥4 or ischemic stroke within the prior 14 days.

Comments: Although 14 days provides a wide window, we strongly encourage enrollment as soon as possible.

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 14-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 14-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. Subjects who have OSA (AHIT3 ≥10, without substantial central sleep apnea), will proceed to the aCPAP run-in night.
2. Subjects who use aCPAP for ≥4 hours, and still do not show substantial central sleep apnea, qualify for randomization.
3. Subject agrees to continue after the run-in night.

Local Site Contact Information

Study Coordinator - Sadie Caldwell 513-558-4503
Project Manager - Emily Sayles 513-503-5284
Principal Investigator- Natalie Kreitzer, MD

Important Contacts

Email Helpline: sleepsmart@umich.edu

To be used for urgent/time sensitive questions regarding enrollment. One of the trial PIs or other investigators will be covering this email from 9am to 8pm Eastern Time.

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