

S.L.E.E.P.:

Studying Life Effects and Effectiveness of Palatopharyngoplasty *(closed to enrollment)*

Why the "SLEEP" Study?

UPPP, the most common surgical treatment for sleep apnea, significantly improves physiologic abnormalities in selected patients. The procedure often does not, however, cure sleep apnea. Consequently, UPPP appears undervalued as a treatment modality for selected sleep-apnea patients.

Recent studies support that UPPP provides clinically important outcomes such as reduced motor vehicle accidents, mortality and incidence of cardiovascular disease. Moreover, health-related quality of life, possibly the most important outcome to patients, barely has been evaluated in UPPP patients. A multi-site, community-based study will adequately demonstrate the treatment effects of UPPP.

Study Aims

(Adults 18 and over)

- To determine whether UPPP improves sleep-related quality of life, measured in Functional Outcomes of Sleep Questionnaire
- To establish whether UPPP affects sleep apnea-related symptoms: snoring, sleepiness or morning headache
- To validate the UPPP Prognostic Staging system (Friedman) for quality-of-life outcomes (measured with Functional Outcomes of Sleep Questionnaire) in UPPP patients.
- To compare quality of life outcomes of UPPP alone versus UPPP with tongue procedure(s) in Friedman Stage II & III patients.

Procedure

The surgeon recruits eligible UPPP patients (most will be eligible) and completes brief eligibility and examination forms within 10 days before surgery. The surgeon has no further responsibilities after mailing the forms to the data coordinating center. The patient completes a baseline questionnaire and home blood pressure measurements within 10 days before surgery. The patient will receive a follow up questionnaire from the coordinating center 3 and 6 months after surgery.

Disease specific-quality of life will be measured with the Functional Outcomes of Sleep Questionnaire at enrollment and at three months post-operatively. Other measures include: global assessment in improvement in sleep apnea; disease-specific quality of life at six months post-procedure; and post-procedure change in secondary problems present at enrollment (sleepiness, snoring, headache, Nasal Obstruction and Septoplasty Effectiveness scale). Since many patients with sleep apnea have multiple sites of obstruction, subjects will be stratified by concomitant procedures with UPPP.

Notes

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