



RESEARCH UPDATES

Rush University Medical Center's ear, nose and throat (ENT) physicians are taking part in a growing number of clinical trials, studying the treatment of head and neck cancer patients with depression; a new procedure to reduce nasal swell bodies that obstruct the patient's airways; and the use of a new radiofrequency current device to treat chronic rhinitis.

"Our department believes in being at the forefront of technology to better treat patients," said Bobby A. Tajudeen, MD, the director of otorhinolaryngology. "The growth of clinical trials in our department speaks to that and speaks to our infrastructure and our continued initiative in researching advancements."

Below are the details of several of these ongoing trials spearheaded by Dr. Tajudeen and Mihir K. Bhayani, MD, FACS, director of the head and neck cancer research program and salivary gland program.

Employing Bupropion to Prevent Depression in Patients with Head and Neck Cancer

Rush ear, nose and throat specialists are holding a randomized, double-blind, placebo-controlled clinical trial to examine the efficacy of administering bupropion to prevent depression in patients undergoing primary therapy for epidermoid carcinoma stages 1 to 4. Bupropion is a first-line antidepressant with an alternative mechanism of action, is not associated with adverse sexual effects or bleeding and has demonstrated its utility in treating cancer-related fatigue.

Fifty-four patients will be selected for one of two groups: one taking bupropion and the other taking a placebo for 12 weeks. Depressive symptoms will be assessed with the Quick Inventory of Depressive Symptomatology, and quality of life (QOL) will be measured using the University of Washington Quality of Life Scale. In line with what has been previously demonstrated for SSRIs, we hypothesize that bupropion therapy will prevent the development of major depressive disorders and improve QOL during primary head and neck cancer treatment.

The Vivaer Procedure for the Treatment of Nasal Swell Bodies for Airway Obstruction

This study is intended to assess the clinical use of the Vivaer ARC Stylus to treat septal swell bodies (SSB) and improve the symptoms of adults diagnosed with nasal obstruction that has been attributed to SSB. The Vivaer ARC Stylus is indicated for use in otorhinolaryngology surgery for the coagulation of soft tissue in the nasal airway and to treat nasal airway obstruction (NAO) by shrinking submucosal tissue, including cartilage in the internal nasal valve area. The Aerin Console is an electrosurgical system that generates radiofrequency electrical current for the use of an Aerin Medical Stylus. The Aerin Console is indicated for use in small clinics, offices and hospitals.

The primary goal of this study is to determine the efficacy of treating the nasal septal swell body area with temperature-controlled radiofrequency current using the Vivaer system for the treatment of NAO. The secondary objective is to evaluate the durability of the treatment's effects over an extended period of 36 months. The study is designed as a multicenter, prospective, open-label and single-arm study.

The RhinAer Procedure for the Treatment of Chronic Rhinitis

Radiofrequency (RF) energy has been used for decades in the fields of otorhinolaryngology, neurosurgery, cardiology, urology and general surgery. Ear, nose and throat surgeons use RF energy in numerous nasal therapies, including RF turbinate reduction (RFTR), which is a minimally invasive surgical option that can reduce tissue volume in a precise, targeted manner. There have been multiple studies analyzing the safety and outcomes of using RF energy in the RFTR procedure. The technique has been shown to be well tolerated and effective.

Aerin Medical previously conducted a small feasibility study (TP220) using the Aerin Medical RF system to treat subjects with chronic rhinitis. The current study looks to provide additional evidence for the effectiveness of the RF procedure by comparing it with a sham procedure in a randomized clinical trial.

Adherence and Outcome of Upper Airway Stimulation for the OSA International Registry

Inspire Upper Airway Stimulation (UAS) is a small, fully implanted system that senses breathing patterns and delivers mild stimulation to maintain multilevel airway openness during sleep. It is used to treat a subset of patients with moderate-to-severe obstructive sleep apnea (OSA) who have an apnea-hypopnea index (AHI) greater than or equal to 15 and less than or equal to 65, who have been confirmed to fail or who cannot tolerate CPAP treatments or bi-level positive

airway pressure machines and who do not have a complete concentric collapse at the soft palate level.

This is a multicenter observational registry. Its purpose is to evaluate the effectiveness of upper airway stimulation by assessing the improvement of patients in the following outcomes:

- Preimplant AHI at baseline compared to the treatment AHI post-implant
- Baseline Epworth Sleepiness Scale (ESS) compared to the ESS post-implant

Secondary registry objectives include collecting therapy adherence data, information on therapy adjustment and titration, and information on the patients' experience with the therapy post-implant. Additionally, it will track clinical global impression at baseline and post-implant, evaluate the acute and long-term safety of upper airway stimulation from the time of the implant to 12 months afterward and evaluate patient-reported new incident comorbid conditions.

Phase 2 Study of OTO-313 Given as a Single Intratympanic Injection in Subjects with Subjective Tinnitus

The purpose of phase 2 of Study OTO-313-201 is to investigate the efficacy and safety of administering 0.32 mg of OTO-313 by intratympanic injection in subjects with unilateral tinnitus. One pharmacotherapeutic approach to treating tinnitus is directed at normalizing altered neural activity within the cochlea. The excessive activation of N-methyl-D-aspartate (NMDA) receptors at the level of the inner hair cell synapses with subsequent deafferentation may be a key mechanism of abnormal sensory signaling in tinnitus.

NMDA receptor antagonists have potential as a local cochlear treatment for tinnitus. Intratympanic administration allows the deposition of drugs over the round window membrane. This enables access to the inner ear for more localized delivery to the cochlea and less systemic drug exposure. Gacyclidine, the active agent in OTO-313, is a noncompetitive NMDA-receptor antagonist.