

Research Updates

RUSH University Medical Center's ear, nose and throat (ENT) physicians have taken part in a growing number of clinical trials, studying several novel treatments for rhinitis, rhinosinusitis and nasal obstruction.

"RUSH is involved in a number of promising, new trials that can potentially make a big impact in patient care," said Bobby A. Tajudeen, MD, the section head of RUSH Rhinology, Sinus Surgery and Endoscopic Skull Base Surgery. "Our participation in these trials speaks to RUSH's commitment to innovation in advancing cutting edge research."

Below are the details of several of these ongoing trials spearheaded by Dr. Tajudeen and Mihir K. Bhayani, MD, FACS, director of otorhinolaryngology research at RUSH.

The Efficacy and Safety of Depemokimab in Patients with Chronic Rhinosinusitis with Nasal Polyps | Active and recruiting

This phase III study is assessing the efficacy and safety of giving 100 mg Depemokimab subcutaneously to patients with chronic rhinosinusitis with nasal polyps.

Chronic rhinosinusitis with nasal polyps is an important clinical entity diagnosed by the presence of both subjective and objective evidence of chronic sinonasal inflammation. Symptoms include anterior or posterior rhinorrhea, nasal congestion, hyposmia and/or facial pressure or pain that can last for greater than 12 weeks. Nasal polyps are inflammatory lesions that project into the nasal airway, are typically bilateral and originate from the ethmoid sinus.

To learn more or to enroll your patient, visit tinyurl.com/RUSH-ANCHOR-1

The Efficacy and Safety of LYR-210 for the Treatment of Chronic Rhinosinusitis | Active and recruiting

This phase III study is evaluating the efficacy and safety of LYR-210, a local, intranasal, anti-inflammatory therapy, for the treatment of chronic rhinosinusitis in adults. LYR-210 is intended to deliver up to six months of continuous mometasone furoate drug therapy to the sinonasal passages.

Chronic sinusitis occurs when a patient's sinuses are swollen and inflamed for three months or longer, despite treatment. This common condition interferes with the way patients' mucus normally drains, causing the nose to feel stuffy. Breathing through the nose may be difficult for patients and the area around their eyes may feel swollen or tender.

Chronic sinusitis, with or without the presence of polyps, is a challenging condition to treat.

Medication is the first line of approach to treat this condition, followed by surgery. Patients with moderate-to-severe chronic rhinosinusitis who had previously failed medical management, but who had not yet had surgery were candidates for this study.

To learn more or to enroll your patient, visit tinyurl.com/RUSH-LYR

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.

Enrollment is currently closed to enrollment and data collected from the trial is currently being evaluated.

To learn more, visit tinyurl.com/RUSH-VIVAER

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.

Enrollment is currently closed to enrollment and data collected from the trial is currently being evaluated.

To learn more, visit tinyurl.com/RHINAER

The Efficacy and Safety of OPN-375 186 µg Twice a Day in Adolescents with Bilateral Nasal Polyps | Active and recruiting

This study is evaluating the efficacy and safety of intranasal administration of OPN-375 186 μ g twice a day versus a placebo in adolescents with bilateral nasal polyposis and nasal congestion.

Nasal polyps are soft, painless, noncancerous growths on the lining of the nasal passages or sinuses, which hang down like teardrops or grapes. They result from chronic inflammation and are associated with asthma, recurring infection, allergies, drug sensitivity or certain immune disorders. Small nasal polyps may be asymptomatic. Larger growths or groups of nasal polyps can block nasal passages and/or lead to breathing problems, a lost sense of smell and frequent infections.

Researchers will evaluate the efficacy of the drug by analyzing the reduction of nasal congestion and obstruction symptoms at the end of the fourth week.

To learn more or to enroll your patients, visit tinyurl.com/RUSH-OPN375