CLINICAL SUMMARY

RhinAer®
Defeat the Drip.

A Prospective, Multi-center, Non-Randomized Study to Evaluate the Quality of Life Impact and Symptoms After Treatment Using Low Power Radiofrequency Energy Applied to the Posterior Nasal Nerve Area for Symptomatic Relief of Chronic Rhinitis

RhinAer® Pivotal Study 24-month Analysis

Published Title

Long-term outcomes following temperature-controlled radiofrequency neurolysis for the treatment of chronic rhinitis

Authors & Investigators

- Dale Ehmer, MD (McKinney, TX)
- Chad M. McDuffie, MD (McKinney, TX)
- Bradley McIntyre, MD (Fort Worth, TX)
- Bryan M. Davis, MD (Colorado Springs, CO)
- Neelesh H. Mehendale, MD (McKinney, TX)
- John H. Willis, MD (Winston-Salem, NC)
- Jeremy P. Watkins, MD (Forth Worth, TX)
- V. Vasu Kakarlapudi, MD (New Albany, IN)*^

**Corresponding author, ^Principal investigator*

Study Overview

This study was an extension of a prospective, single-arm, multi-center study[1] designed to collect long-term outcomes for patients undergoing temperature-controlled radiofrequency neurolysis (RhinAer) of the posterior nasal nerve (PNN) for the treatment of chronic rhinitis. Thirty-four (34) patients were included in this study extension and completed the 24-month follow-up visit, which assessed change in reflective Total Nasal Symptom Score (rTNSS), treatment-related adverse events, rTNSS responder rate, and various quality-of-life (QoL) and patient satisfaction measures. Mean rTNSS significantly decreased from 8.4 at baseline to 2.9 at 24 months ($p<0.001$), representing a 65.5% improvement. Similar trends in improvements were observed for all rTNSS sub-scores (rhinorrhea, nasal congestion, itching, sneezing), including postnasal drip and cough scores. No serious adverse events with a relationship to the device and/or procedure occurred. The outcomes of this study demonstrate that RhinAer results in a significant and durable reduction in the symptom burden of chronic rhinitis through 24 months post-procedure.

[1]Ehmer D, McDuffie CM, Scurry WC, et al. Temperature-Controlled Radiofrequency Neurolysis for the Treatment of Rhinitis. American Journal of Rhinology & Allergy. 2022;36(1):149-156. doi:10.1177/19458924211033400

Objective

To evaluate the long-term safety and effectiveness of RhinAer treatment on the PNN to address chronic rhinitis.

Outcome measures

Primary endpoint

- Mean change in rTNSS from baseline to 24-months post-procedure
- rTNSS responder rate, defined as ≥30% improvement from baseline to 24-months post-procedure
- Percentage of participants with a positive response on QoL assessment items at 24-months post-procedure
- Mean score on a patient satisfaction survey at 3-, 12-, and 24-months post-procedure
- Percentage of participants with treatment-related adverse events (safety) during the 12-24-month extended follow-up period

Patient eligibility

Key inclusion criteria

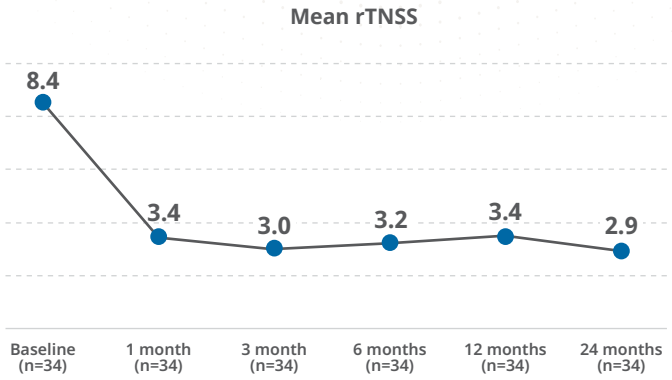
- Age 22-75 years
- Chronic rhinitis symptoms of at least 6 months duration
- rTNSS ≥6
- Rhinorrhea rTNSS rating ≥2
- Nasal congestion rTNSS rating ≥1
- Patient dissatisfaction with medical management

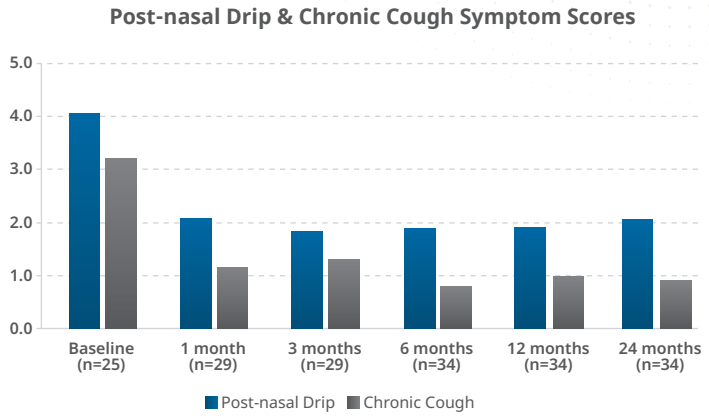
Key exclusion criteria

- Nasal anatomic abnormalities or obstructions that could restrict access to the treatment site
- Rhinitis medicamentosa, active nasal/sinus infection, history of nose bleeds, ocular allergic symptoms, or history of dry eye

KEY FINDINGS

RhinAer delivered durable improvements across all chronic rhinitis symptoms



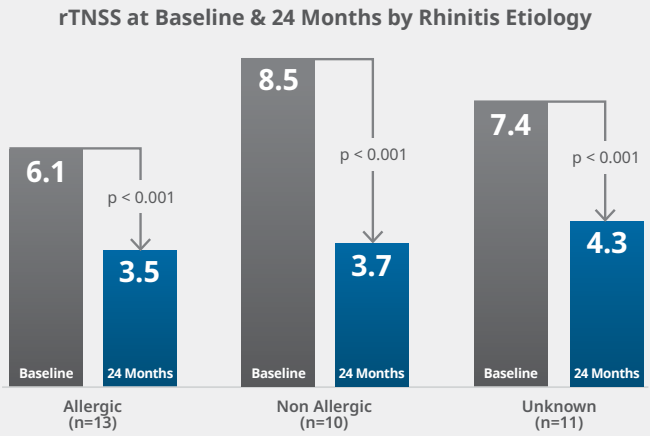


- Treatment improved mean rTNSS score from 8.4 at baseline to 3.4 at 12 months and sustained improvement to 2.9 at 24 months (p<0.001)
- 88.2% of patients experienced a significant (p<0.001) and sustained reduction in their chronic rhinitis symptoms through 24 months

- Post-nasal drip and chronic cough symptom scores remained statistically significantly improved from baseline at 24 months (p<0.001)
- All rTNSS sub-scores (rhinorrhea, nasal congestion, nasal itching, and sneezing) measured statistically significant improvements (p<0.001) over baseline at 24 months, representing an overall rTNSS decrease of 65.5%

RhinAer delivered symptom improvement in chronic rhinitis of allergic, non-allergic, and unknown etiologies

- Treatment resulted in statistically significant mean rTNSS improvements for patients suffering from chronic rhinitis of allergic, non-allergic, and unknown etiologies (p<0.001)



Treatment with RhinAer was well-tolerated and significantly improved patients' quality of life

- No serious adverse events related to the device and/or procedure were observed in the 12-24-month period
- Procedure tolerability, ease of recovery, nasal breathing improvement, satisfaction with the procedure, and likelihood to recommend RhinAer were all high at 3 months and sustained through 24 months
- Patients experienced better sleep quality at 24 months post-procedure, with 58.8% never or rarely having difficulty falling asleep and 50.0% very frequently or frequently having good sleep throughout the night

ClinicalTrials.gov: https://clinicaltrials.gov/ct2/show/NCT04684875

Allergy & Rhinology: https://journals.sagepub.com/doi/full/10.1177/21526575221096045

Please scan QR code to access the full online publication

Indication for use: The RhinAer® Stylus is indicated for use in otorhinolaryngology (ENT) surgery for the destruction of soft tissue in the nasal airway, including in posterior nasal nerve regions in patients with chronic rhinitis

To learn more about RhinAer, please visit RhinAer.com

Aerin® MEDICAL