CLINICAL SUMMARY

RhinAer™
Defeat the Drip.

CLINICAL EVALUATION OF LOW POWER RADIOFREQUENCY ENERGY APPLIED TO THE POSTERIOR NASAL NERVE AREA FOR SYMPTOMATIC RELIEF OF CHRONIC RHINITIS

RhinAer® Pivotal Study 52-week Analysis

Published Title

Temperature-controlled Radiofrequency Neurolysis for the Treatment of Rhinitis

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Study Overview

This prospective, multi-center, non-randomized study was conducted to evaluate the safety and efficacy of the RhinAer® Stylus (RhinAer) on patients with chronic rhinitis symptoms for at least 6 months duration. A total of 50 subjects were treated with RhinAer across 5 US centers and followed-up at 2, 4, 12, 26, and 52 weeks post-procedure. Due to two patients withdrawing consent after 12 weeks and one patient lost to follow-up after 26 weeks, 47 patients (94%) completed their 52-week follow-up, which assessed change in reflective Total Nasal Symptom Score (rTNSS), treatment related adverse events, rTNSS responder rate, and various quality-of-life (QoL) measures. Mean rTNSS significantly decreased from 8.5 at baseline to 3.6 at 52 weeks ($p<0.001$), representing a 57.6% improvement. Similar trends in improvements were observed for all rTNSS sub-scores (rhinorrhea, nasal congestion, itching, sneezing), postnasal drip scores, and chronic cough scores. No serious adverse events with a relationship to the device and/or procedure occurred. The results of this trial demonstrate that RhinAer is safe and effective for the treatment of chronic rhinitis and resulted in a durable improvement in symptoms through the 52-week follow-up.

Objective

To evaluate safety and efficacy through 52 weeks in adults diagnosed with chronic rhinitis and treated with RhinAer.

Outcome measures

Primary endpoint	Other endpoints
• Change in rTNSS at baseline and 12 weeks post-procedure • Percentage of participants with treatment-related adverse events (safety)	• rTNSS responder rate, defined as ≥30% improvement relative to baseline • Change in rTNSS over time • Change in rTNSS individual nasal symptom component scores over time

Patient eligibility

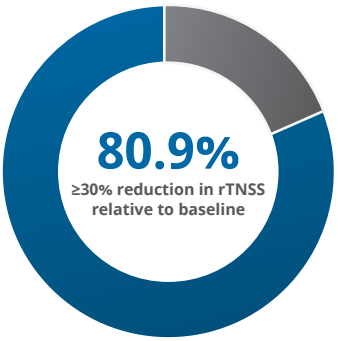
Key inclusion criteria	Key exclusion criteria
• Age 22-75 years • Chronic rhinitis symptoms of at least 6 months duration • rTNSS rating: overall ≥6, rhinorrhea ≥2, nasal congestion ≥1 • Patient dissatisfaction with medical management, including poor response to nasal steriod	• Nasal anatomic abnormalities 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 TAKEAWAYS

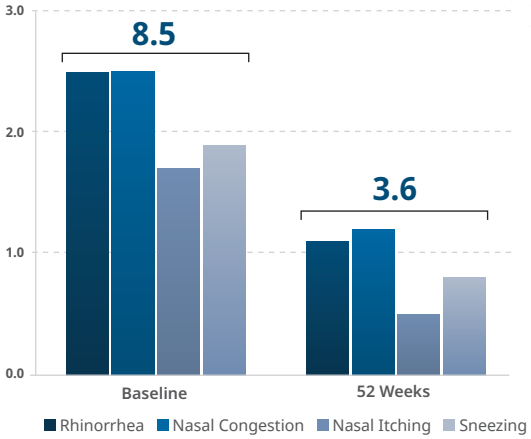
RhinAer delivers durable improvements across all chronic rhinitis symptoms

- Treatment improved mean rTNSS score from 8.5 at baseline to 3.4 at 12 weeks and sustained improvement to 3.6 at 52 weeks (p<0.001)

Responder Rate at 52 Weeks



rTNSS Sub-scores Baseline vs. 52 Weeks

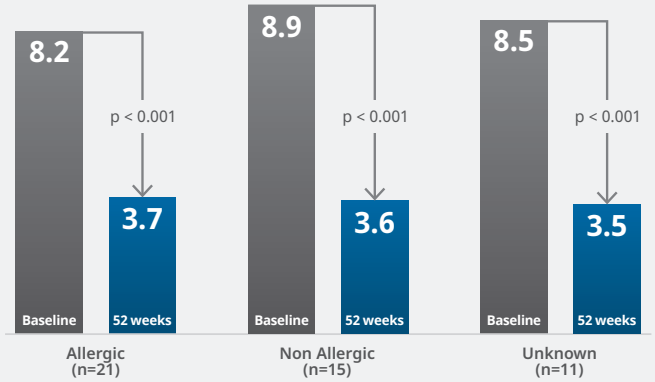


- 80.9% of patients experienced a significant (p<0.001) and sustained reduction in their chronic rhinitis symptoms through 52 weeks
- 100% of patients experienced at least one rTNSS point improvement at 52 weeks relative to baseline, demonstrating that all patients experienced some measurable symptom relief
- All rTNSS sub-scores (rhinorrhea, nasal congestion, nasal itching, and sneezing) measured statistically significant improvements (p<0.001) over baseline at 52 weeks, representing an overall rTNSS decrease of 57.6%
- Post-nasal drip and chronic cough symptom scores remained statistically significantly improved from baseline at all follow-up time points (p<0.001)

RhinAer delivers 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)

rTNSS at Baseline & 52 Weeks by Rhinitis Etiology



RhinAer is a well-tolerated treatment that can be performed safely to reduce the symptoms of chronic rhinitis

- No serious adverse events related to the device and/or procedure were observed
- No device- or procedure-related headaches were reported through 52 weeks
- A total of 16 adverse events that were considered possibly device- or procedure-related occurred, with all except two (sinusitis and worsening dry eye) resolved by 52 weeks

ClinicalTrials.gov: https://clinicaltrials.gov/ct2/show/NCT03727347

American Journal of Rhinology & Allergy: https://journals.sagepub.com/doi/full/10.1177/19458924211033400

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

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