

Clinical Study Results

Cryosurgery in the Nasal Passageway for Adults with Chronic Rhinitis



STUDY OVERVIEW

A prospective, multicenter clinical study performed in the United States to support the indication for adults with chronic rhinitis. Twenty-seven subjects were enrolled and cryosurgery was successfully performed with the ClariFix® device bilaterally (n=54 treatments) while the subjects were awake using local or topical anesthesia. Cryosurgery was well-tolerated, no device or procedure-related SAEs were reported in the study. Subjects' rhinitis scores (reflective Total Nasal Symptom Score (rTNSS)) improved 56% at 90 days, and improvement was maintained at 1 year for subjects not lost to follow-up. Clinical study results demonstrated that both the safety profile and effectiveness results achieved by the ClariFix device in adults with chronic rhinitis are comparable to that reported in published literature on cryosurgery in the nasal passageway.

PURPOSE

To evaluate the use of the ClariFix device as a cryosurgical tool used in the nasal passageway of patients with Chronic Rhinitis.

INDICATIONS FOR USE

US (FDA): The ClariFix Device is intended to be used as a cryosurgical tool for the destruction of unwanted tissue during surgical procedures, including in adults with chronic rhinitis.

PRIMARY ENDPOINTS

- Frequency of device- and procedure-related serious adverse events (SAEs) through 1 year follow-up
- Subject assessment of nasal symptoms using rTNSS and VAS (Visual Analogue Scale) at baseline and at 7, 30, 90, 180 and 365 post-treatment

SECONDARY ENDPOINTS

- Frequency of device- and procedure-related adverse events (AEs) through 1 year follow-up
- Physician evaluation of ease of cryoablation using the ClariFix device

SUBJECT DEMOGRAPHICS

- Age range: 27 – 87 years
- Average age: 53 years old
- 63% female, 37% male
- 13 subjects had positive allergy tests
- 13 subjects had negative allergy tests
- Pre-treatment average rTNSS score: 6.2

Key Inclusion Criteria

- >21 years of age
- Moderate to severe symptoms of rhinorrhea and/or nasal congestion for >3 months

Key Exclusion Criteria

- Clinically significant anatomic obstructions that limit access to the posterior nose including severe septal deviation, nasal polyps, and sinonasal tumor
- Septal perforation or prior sinus or nasal surgery altering the anatomy of the posterior nose
- Anti-coagulant use

SAFETY

- No device or procedure-related SAE's
- One subject reported moderate nasal bleeding at Day 27 that was controlled with standard nasal packing and cautery. The investigator deemed it to be remotely related to the device as the target treatment location was completely healed during endoscopic examination at Day 7.
- Other adverse events commonly associated with healing after cryosurgery in the nasal passageways (pain/discomfort, headache, facial pain, bleeding, dry nose and ear blockage) were observed and by day 90, they had either self-resolved or the remaining events rated as mild with a probable cause relating to pre-existing conditions.

Well tolerated, safe outcomes



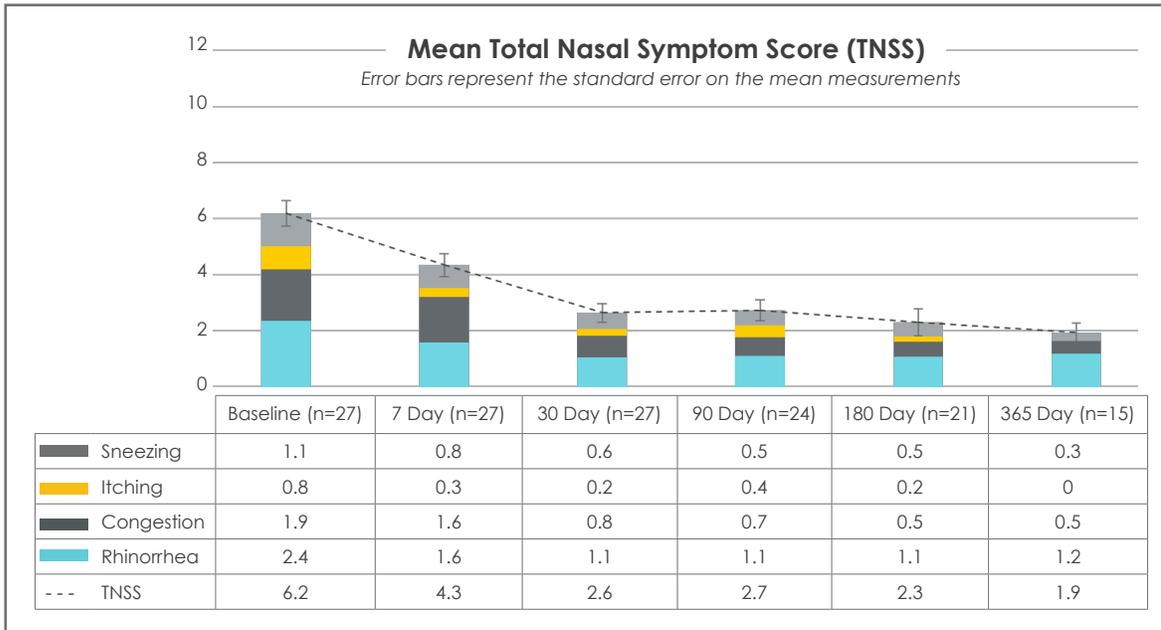
RESULTS

Primary endpoint analysis demonstrated:

- Average per patient rTNSS improved 46% from baseline to 90 days (0=minimum score, 12=maximum score)
- Average VAS score improved 53% from 7.6 at baseline to 3.7 at 90 days (0=minimum score, 10=maximum score)

Secondary endpoint analysis demonstrated:

- Investigators rated cryosurgery using the ClariFix device as “easy” to “moderately easy” in 89% (24/27) of the subjects and “moderately difficult” in 11% (3/27) of the subjects



4 out of 5 patients reported long-lasting improvement

Largest reduction in rhinorrhea and congestion symptoms

Rhinorrhea

Statistically significant reduction 30, 90, 180 and 365 days post-treatment ($p < 0.001$)

Congestion

Statistically significant reduction 30, 90, 180 and 365 days post-treatment ($p < 0.001$)

Efficacious in both ALLERGIC and NON-ALLERGIC populations

