

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

KEY INCLUSION CRITERIA

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

KEY EXCLUSION CRITERIA

- Subjects with clinically significant anatomic obstructions that limit access to the posterior nose including severe septal deviation, nasal polyps, and sinonasal tumor.
- Subjects with a septal perforation or prior sinus or nasal surgery altering the anatomy of the posterior nose
- Subjects on anti-coagulants

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 test results
- Pre-treatment average rTNSS score: 6.2

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

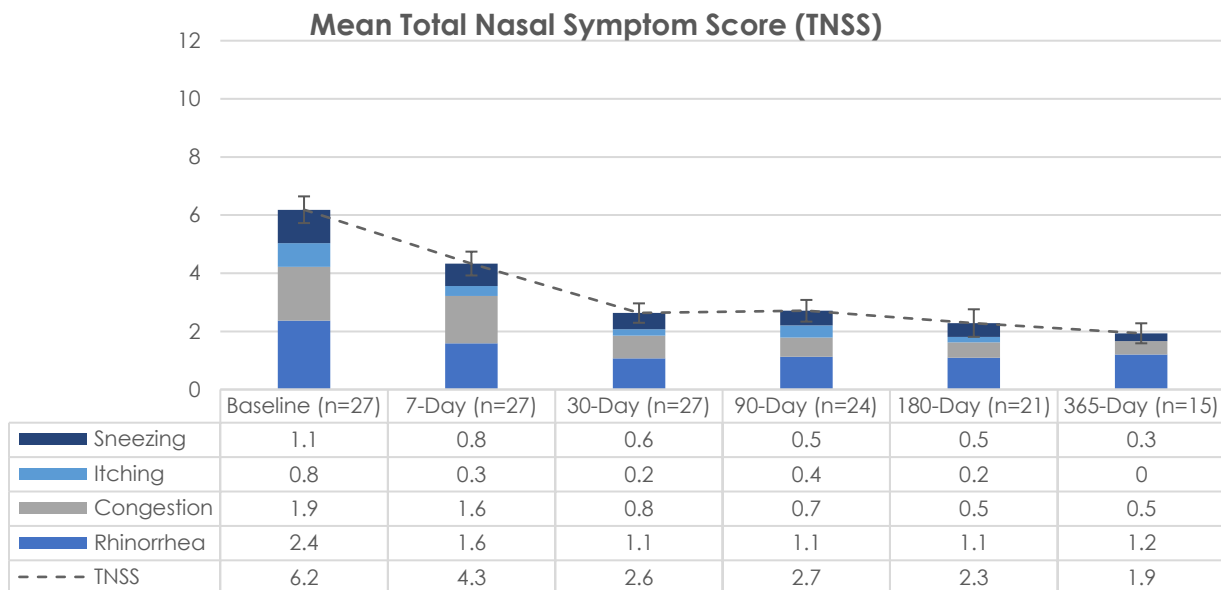
Results

The primary endpoint analysis demonstrated:

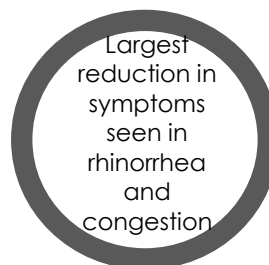
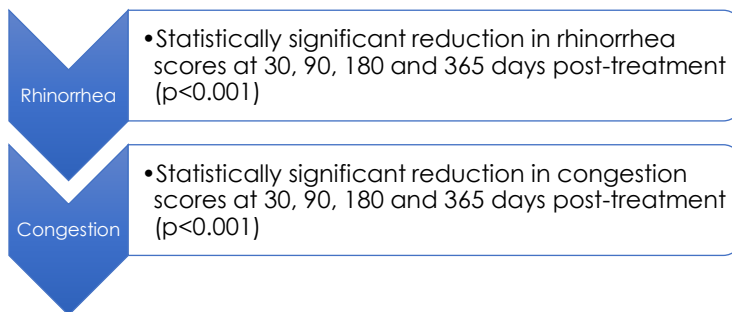
- The average rTNSS improved 56% from 6.2 at baseline to 2.7 at 90 days (0 = minimum score, 12 = maximum score).
- The average VAS score improved 53% from 7.6 at baseline to 3.7 at 90 days (0 = minimum score, 10 = maximum score).

The secondary endpoint analysis demonstrated:

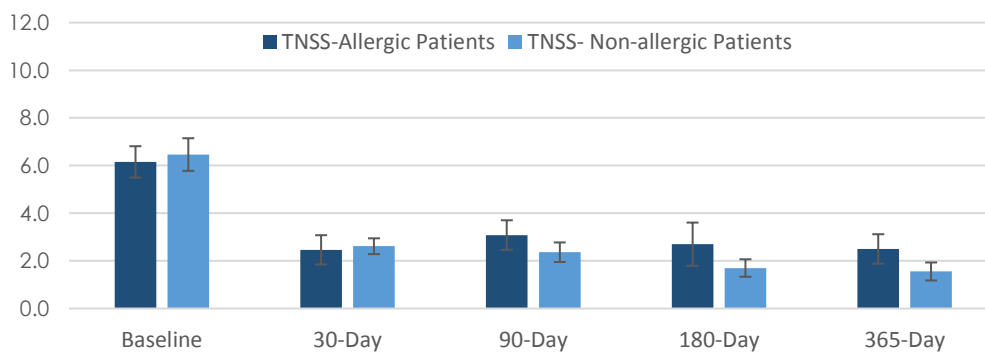
- Investigators rated cryosurgery using the ClariFix device as “easy” to “moderately easy” in 89% (24/27) of the subjects and “moderately difficult” in 11% (3/27) of the subjects.



Error bars represent the standard error on the mean measurements.



Mean TNSS Scores in Allergic vs Non-allergic Patients¹



Allergic Patients: N=13 at baseline, 30-Day and 90-Day follow-up, n=10 at 180-Day follow-up and n=6 at 365-Day follow-up.

Non-Allergic Patients: N=13 at baseline & 30-Day follow-up, n=11 at 90-Day follow-up, n=10 at 180-Day follow-up and n=9 at 365-Day follow-up

 Arrinex, Inc.

Redwood City, CA 94063

Arrinex.com

© 2017 Arrinex

Data on file per Arrinex Report: A2014-02 TR530, Rev D