KNEE PAIN REDUCTION POST-MARKET CLINICAL STUDY

iovera° HEALTH

STUDY OVERVIEW

PURPOSE

To evaluate the use of the Focused Cold Therapy delivery system for the temporary relief of knee pain per the indications for use.

INDICATIONS FOR USE

US (FDA): The iovera° system is used to destroy tissue during surgical procedures by applying freezing cold. It can also be used to produce lesions in peripheral nervous tissue by the application of cold to the selected site for the blocking of pain. The iovera° system is not indicated for treatment of central nervous system tissue.

EU and Canada: The myoscience iovera° system is a cryosurgical device for treating superficial and subcutaneous tissue structures. Applications for iovera° health include temporary pain reduction, treatment of dermatologic conditions, and focal cryo-treatment of tissue.

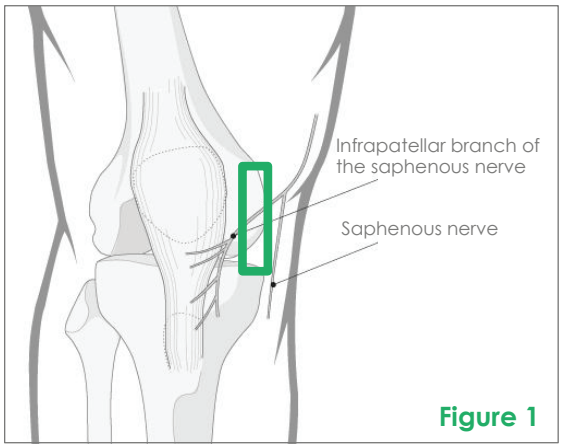


Figure 1

PRIMARY ENDPOINT

Improvement in Visual Analog Scale (VAS) score at day 7 post treatment.

SECONDARY ENDPOINTS

1. Improvement (pain, stiffness, and functionality) as determined by the Western Ontario and McMaster Osteoarthritis Index (WOMAC) Scale at Day 7. A significant difference is observed as ≥ 2-points.
2. Duration of Treatment Effect.

KEY INCLUSION CRITERION

- Adults suffering from knee pain with an average VAS pain score of ≥ 4 for prior 30 days.

KEY EXCLUSION CRITERIA

- Subjects with full or partial knee replacements
- Subjects who had systemic injections in the last 6 months
- Subjects who had concomitant inflammatory disease (e.g. rheuymatoid arthritis)

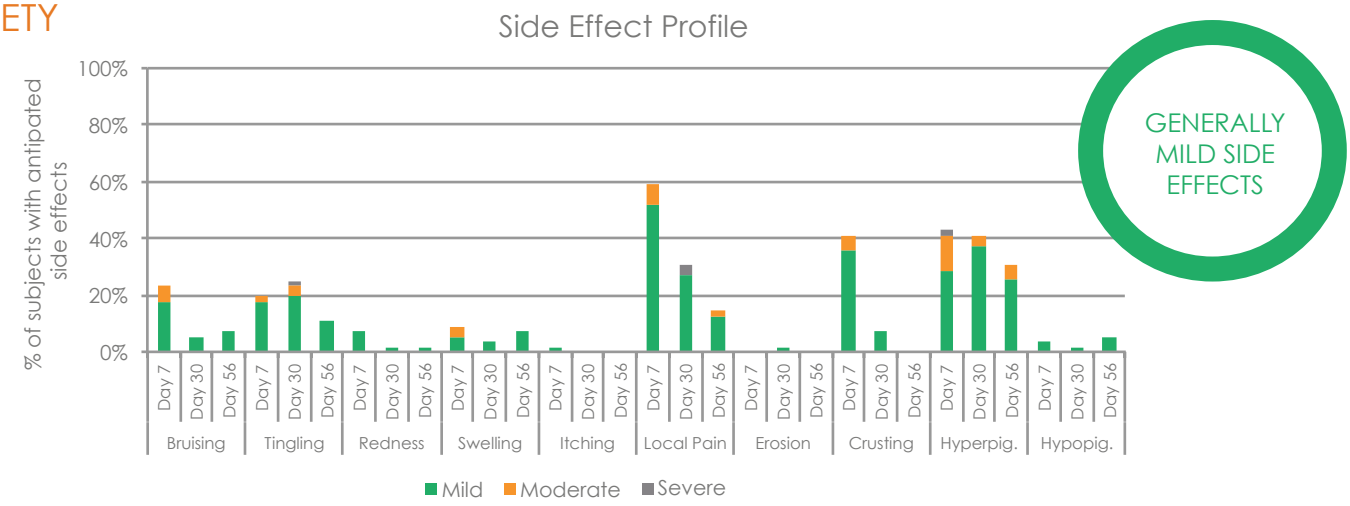
SUBJECT DEMOGRAPHICS

- Age range: 30-82 years
- Average age: 56 years old
- 64% male, 36% female
- Average pre-treatment VAS score: 6.3
- Average pre-treatment overall WOMAC score: 125.8
  - Pain: 25.2; Stiffness: 11.8; Function: 88.8

METHOD

33 subjects were enrolled and treated at two investigational sites in the USA. Enrollment for the study began September 18, 2012 and was completed March 25, 2013. Subjects received treatment, on one or both knees, to the infrapatellar saphenous nerve, or ISN (Figure 1). Treatment sites were identified using anatomic landmarks and palpation.

SAFETY



Anticipated side effects reported per knee in the treatment area at 7, 30 and 56 day follow-ups. N=56 knees at 7 and 30 days; N=55 knees at 56 days.

ADVERSE EVENTS

- 9% (3/33) of subjects had a total of 4 procedure related events. These included right leg numbness, left leg numbness, both reported from the same, and nausea during the procedure. These were assessed by the Investigator as definitely related. Tingling/pain in feet was assessed as possibly related.
- All procedure-related adverse events were mild to moderate and resolved without intervention.
- One serious adverse event was reported and assessed by the investigator as unrelated to the device or procedure.
- There were no device-related adverse event reports (i.e. malfunction).

See reverse page for more information

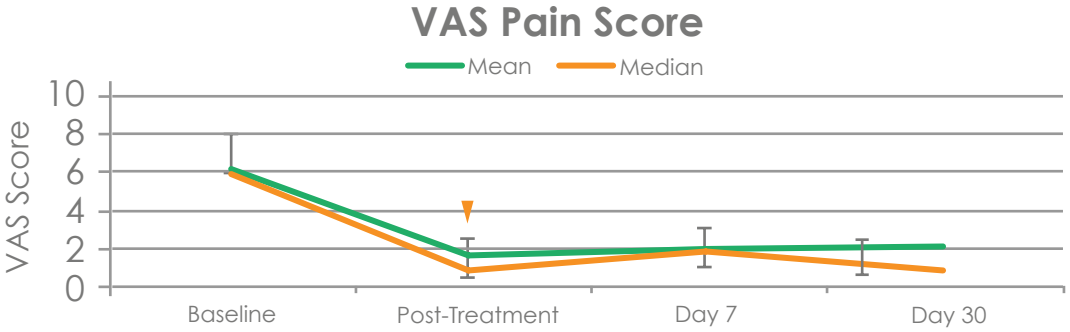
RESULTS

The primary endpoint analysis is as follows:

- Effectiveness: At Day 7, 91% of Subjects had at least a one point improvement in VAS score for pain; 88% of Subjects also had a clinically important improvement of at least two points at the same follow-up. Improvement in VAS from baseline scores was statistically significant post-treatment (P=4.35E-14), at Day 7 (P=2.06E-12) and at Day 30 (P=1.82E-10)

The secondary endpoint analysis is as follows:

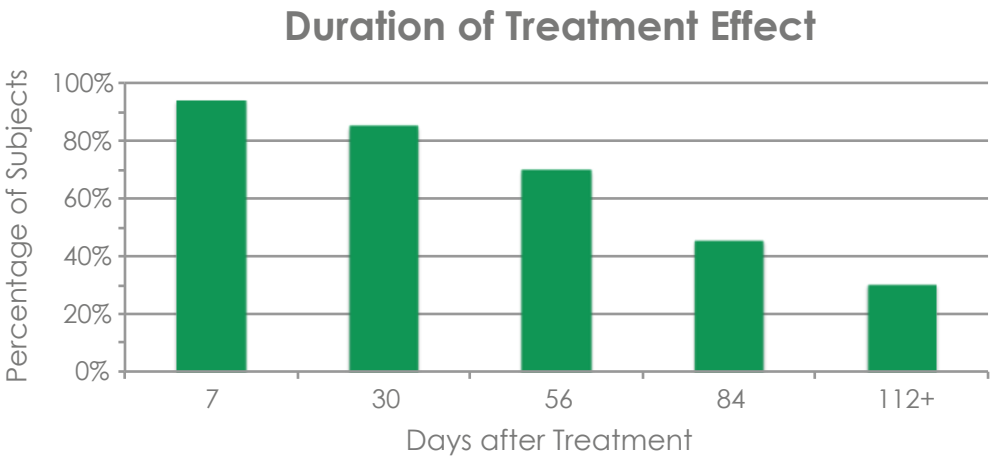
- WOMAC: 77% of Subjects had a clinically important improvement of ≥2 points per question on average. Improvement in WOMAC from baseline was statistically significant (P=7.53E-17).
- Duration of Treatment Effect: 70% of Subjects reported an effect at Day 56.



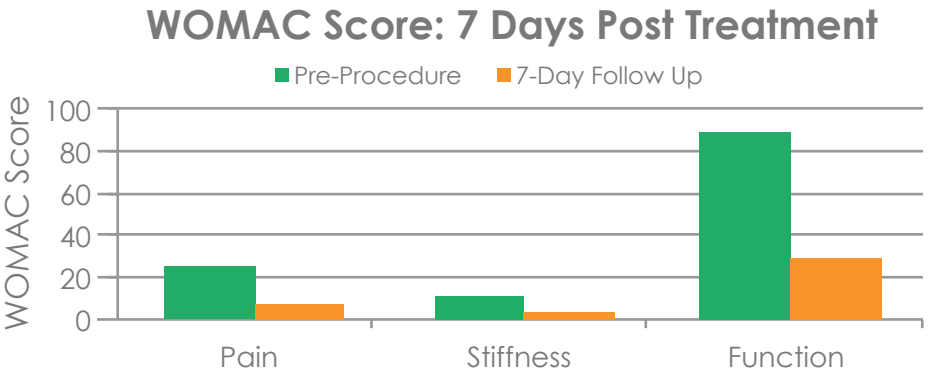
VAS SCORE REDUCED BY AVERAGE OF ▼**4.5 POINTS** IMMEDIATELY FOLLOWING TREATMENT

Error bars represent the standard error on the mean measurements. N=33 subjects at baseline, post-treatment and 7 days; N=32 subjects at 30 days.

OVER **80%** OF SUBJECTS SHOWED A **CLINICALLY IMPORTANT IMPROVEMENT** AT 30 DAYS[1]



Note: Only subjects reporting effect at 56 days post-treatment were assessed beyond that point.



AT 30 DAYS, **94%** OF SUBJECTS REPORTED THEY WOULD **HAVE THE TREATMENT AGAIN**

Average WOMAC scores for Pain, Stiffness and Function comparing baseline assessment to 7 days post-treatment; N=56 knees. Total possible WOMAC scores: 50 (Pain), 20 (Stiffness), 170 (Function).

[1]Gallagher, J., Liebman, M., and Bijur, P. (2001). Prospective validation of clinically important changes in pain severity measured on visual analog scale. Ann Emerg Med. 38:6;633-638.

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