Taking Spinal Cord Stimulation beyond Failed Back Surgery Syndrome: Design of a Multicenter RCT for Non-Surgical Refractory Back Pain (NSRBP)

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Introduction

- Few treatment options exist for chronic back pain patients who have failed conventional medical management (CMM) and are not candidates for back surgery (1). We refer to this population as non-surgical refractory back pain (NSRBP) patients.
- Spinal cord stimulation (SCS) is most frequently used to treat patients who have failed surgical intervention, a population that has been addressed in at least 3 randomized controlled trials (RCT) (2-4).
- A single-center study has shown that high frequency SCS (HF-SCS) at 10 kHz is effective long-term in the NSRBP population (5), but currently, no level 1 evidence exists.
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Objectives

Compare treatment with HF-SCS at 10 kHz plus CMM to CMM alone in terms of clinical- and cost-effective as treatment for chronic refractory back pain in patients who are surgery naïve and are deemed by a spine- or neuro-surgeon unlikely to benefit from surgery.

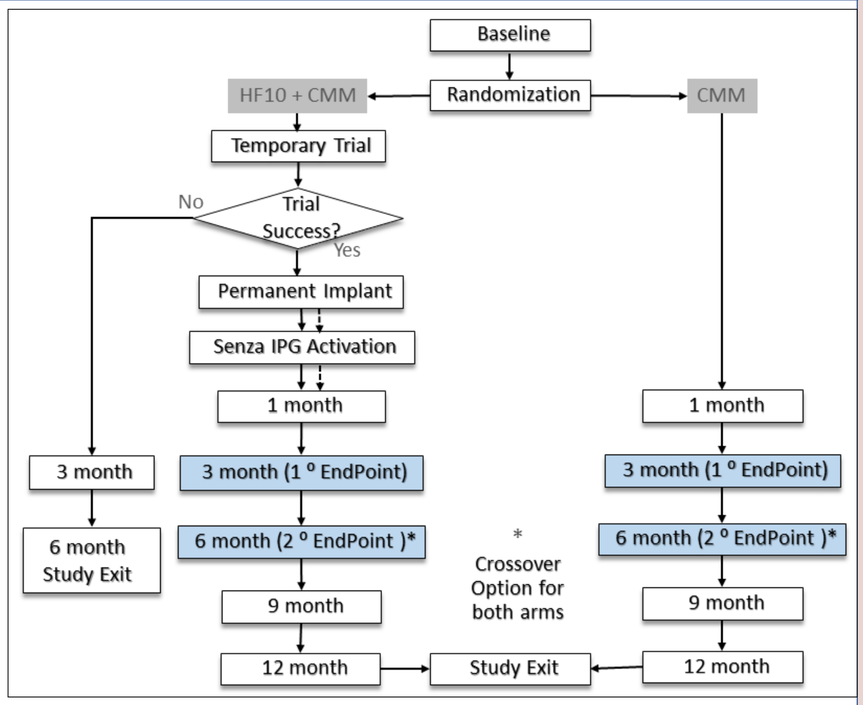
Common diagnosis in this patient group are shown in Table 1. Note that patients may have multiple diagnoses.

Table 1.

Common Diagnosis in NSRBP Population
Lumbar facet arthropathy with axial back pain
Lumbar radiculopathy without causal nerve impingement/significant foraminal narrowing
Lumbar spinal stenosis with back pain
Discogenic Pain

Materials & Methods

Treatment with CMM will be randomized 1:1 against HF-SCS at 10 kHz plus CMM in a multicenter open-label randomized controlled study. CMM is defined as appropriate medical management, determined by the investigator to be the best standard of care for each individual subject. Institutional Review Board approval and written informed consent will be obtained at each site prior to patient screening and enrollment.



Primary endpoint: Proportion of subjects in each treatment group achieving ≥50% pain relief compared to baseline. **Secondary endpoint:** comparison of treatment groups in terms of disability, pain, global impression of change, quality of life and opioid equivalent medication dosage.

Table 2. The primary study screening criteria.

Inclusion	Exclusion
1. Have been diagnosed with chronic, refractory axial low back pain with a neuropathic component and are not eligible for spine surgery	1. Have a diagnosed back condition with inflammatory causes of back pain, serious spinal pathology and/or neurological disorders
2. Have not had any surgery for back or leg pain, or any surgery resulting in back or leg pain	2. Have a medical condition or pain in other area(s), not intended to be treated in this study
3. Qualifying pain score	3. Any diagnosis or known condition that can impact reporting of study outcomes as determined by the Investigator
4. Be on stable pain medications, as determined by the Investigator	4. Be benefitting within 30 days prior to enrollment from an interventional procedure to treat back and/or leg pain

Materials & Methods (contd.)

After 6 months, there will be an opportunity for participants to ***cross over*** to the other treatment group (**Figure 1**). Outcome data **(Table 3)** will be collected and analyzed at baseline, 3, 6, 9, and 12 months.

Table 3. Outcomes
Pain Relief
Visual Analog Scale Pain Type
Quality of Life
Health related quality of life Global Impression of Change Sleep Mental health
Opioid Use
Opioid equivalent dose Opioid side effects
Disability
Oswestry Disability Index
Health Care Utilization

Results: Study Status

Institutional Review Board approval has been obtained for the first sites. Enrollment is expected to continue through 2019.

Conclusions

This study is significant in that it will provide level 1 evidence to guide treatment options for surgery naïve patients with refractory back pain, who are ineligible for surgery.

References

1. Koes BW et al. Expert Opin Pharmacother. 2018;19(6):537-45.
2. North RB et al. Neurosurgery. 2005;56(1):98-106; discussion -7.
3. Kumar K et al. Neuromodulation. 2005;8(4):213-8.
4. Kapural L et al. Anesthesiology. 2015;123(4):851-60.
5. Al-Kaisy et al. Pain Med. 2018;19(6):1219-26