Design of a Multicenter Randomized Controlled Study Comparing Clinical- and Cost-effectiveness of Spinal Cord Stimulation at 10 kHz to Best Medical Management for Treatment of Refractory Back Pain in Surgically Naïve Patients

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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. Some payers limit spinal cord stimulation (SCS) reimbursement only to patients who have failed surgical intervention, a population that has been addressed in at least 3 RCTs (2,3,4). A small feasibility study has shown that SCS at 10 kHz (SCS-10kHz) is effective in the NSRBP population (5), but no level 1 evidence exists.

Study Rationale

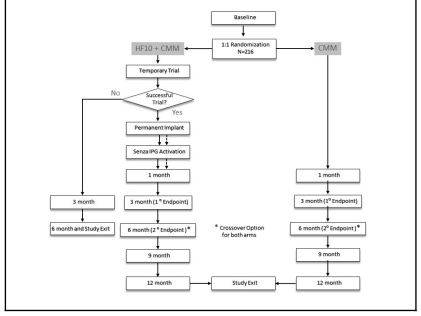
The study will provide evidence to clinicians and healthcare payers comparing SCS-10kHz plus CMM therapy to CMM alone terms of pain relief and quality of life measures, and improved cost-effectiveness.In this study, CMM is appropriate medical management as determined by the investigator to be the best standard of care for each individual patient. Treatment with CMM will be randomized 1:1 against SCS-10kHz plus CMM.

Study Design

The primary endpoint will be proportion of subjects in each treatment group achieving at least 50% back pain relief compared to baseline. The secondary endpoints will comparatively analyze SCS-10kHz vs CMM in terms of patient reported outcomes (disability, impression of change in overall health condition, health related quality of life), and change in opioid equivalent medication usage. Health care utilization and work status will be used in a cost-effectiveness analysis. The rate of treatment related adverse events will be compared.

Table 1 shows the main outcomes that the study will measure.

Figure 1



The study flow is shown in **Figure 1**. After consent, the patients who meet eligibility requirement will be randomized to either HF10 + CMM or CMM alone. The HF10 + CMM arm will be trialed for SCS, and if the > 50% pain relief succes criteria is met, will go on to permanent implant, and IPG activation. Patients in the CMM arm will continue to recieve medical management that they were recieving prior to study entry. After 6 months, there will be an opportunity for participants to cross over to the other treatment group. Outcome data will be collected and analyzed at baseline, 3, 6, 9, and 12 months.

Table 1

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

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.

Learning Objectives

By the conclusion of the session, participants should be able to
1) Describe the state of evidence for SCS in refractory back pain without previous surgery.
2) Identify SCS as a potential treatment, important outcomes, current challenges.

References

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