Spinal Cord Stimulation (SCS) has been shown to be an effective treatment option for the treatment of chronic intractable pain since the 1990s. This has relied on the understanding that effective pain relief may be obtained by employing stimulation without paresthesia at high frequency settings up to 10 kHz. 2, 3 Additionally, other ways of employing stimulation without paresthesia are also being studied. 4

Boston Scientific Corporation sponsored ACCELERATE study is designed to evaluate the safety and effectiveness of high rate spinal cord stimulation (HR-SCS) as compared with commercial rate stimulation (CR-SCS) in patients with chronic intractable pain of the trunk using the Precision Spinal Cord Stimulator (SCS) System Adapted for High Rate SCS.

ACCELERATE is a multi-center, randomized, controlled, open label study with a crossover design. In this crossover design, eligible subjects are randomized 1:1 to receive one of the following sequences:

- CR-SCS followed by HR-SCS
- HR-SCS followed by CR-SCS

Following completion of Period 2, subjects will be followed up to 1 year in long term follow up.

**Methods**

Subjects will receive a Boston Scientific Corporation Precision Spinal Cord Stimulator System Adapted for High-Rate Spinal Cord Stimulation (PRECISION SCS System for HR) implant upon completion of screening.

Adverse events including device or procedure related events, serious adverse events and unanticipated adverse device events will be collected during the study.

The following endpoints below will be collected during the study:

**Primary Endpoint:**

Comparison of low back pain responder rate in the HR-SCS group to that of the CR-SCS group at 3 months post-activation, based on reduction from Baseline in average low back pain intensity.

**Secondary/Exploratory Endpoints:**

Include changes in overall pain intensity, quality of life, global impression of change, sleep quality and disability during study follow up as compared with Baseline.

**Key Inclusion Criteria:**

- Complaint of persistent or recurrent low back pain, with or without equal or lesser leg pain, for at least 180 days prior to Screening
- If taking prescription opioids for primary chronic pain complaint (low back and/or leg pain), must have been on a stable prescription (same drug(s) and dose(s)) for 30 days prior to Screening
- Willing and able to comply with all protocol-required procedures and assessments/evaluations
- 22 years of age or older when written informed consent is obtained
- Subject signed a valid, IRB-approved informed consent form (ICF) provided in English
- Adequate contraception
- Will complete an electronic pain diary

**Key Exclusion Criteria:**

- Significant cognitive impairment at Screening, that in the opinion of the Investigator, would reasonably be expected to impair the study candidate’s ability to assess pain intensity and/or complete an electronic pain diary
- A female who is breastfeeding
- A female of childbearing potential planning to get pregnant during the course of the study or not using adequate contraception

The ACCELERATE study will report the patient outcomes of the use of the Precision SCS system at high rate settings as compared with commercial SCS settings in the management of chronic intractable pain of the trunk.

- Study is currently ongoing
- A total of 406 subjects at up to 20 sites to be included in the study
- The use of high rate SCS will provide patients the option of receiving subperception SCS in the treatment of their pain.
- The availability of such options with Spinal Cord Stimulation may widen the treatment armamentarium for patients and physicians.

**References**


