DTM™ Spinal Cord Stimulation (SCS) Randomized Controlled Trial

Clinical summary

12-Month results from the On-label, Prospective, Multicenter, Randomized Controlled Trial Comparing DTM™ SCS to Conventional SCS.


Overview

Twelve-month results of the DTM™ SCS RCT using the Medtronic Intellis™ SCS neurostimulator to compare the effectiveness and safety of DTM™ SCS programming to conventional programming in patients with chronic intractable back pain (≥ 5) with moderate to severe leg pain.

Primary endpoint

Back pain responder rate, defined as percentage of subjects with a decrease of at least 50% in back pain VAS relative to baseline, at 3 months (non-inferiority comparison between DTM™ SCS and conventional SCS).

Secondary objectives

- To compare back pain responder rate in a statistical test of superiority
- To compare back and leg pain relief as measured by VAS at 3 and 12-months
- To characterize adverse events at all follow up periods

Descriptive analysis

Percentage of patients with profound back pain relief at 3 and 12 months, defined as a decrease of at least 80% in back pain VAS.

Superior Pain Relief compared to conventional stimulation

Key takeaways

- The primary endpoint was statistically significant for both noninferiority (p < 0.0001) as well as for superiority (p = 0.0010), with a back pain responder rate of 80% for DTM™ SCS and 51% for conventional SCS (n = 96 subjects).
- Statistically significant and superior back pain relief with DTM™ SCS compared with conventional stimulation was sustained at 12 months (p = 0.0005).
- Outcomes at the 12-month follow-up (n = 79 subjects) included:
  - 84% back pain responder rate with DTM™ SCS
  - 69% of patients were profound back pain responders (≥ 80% pain relief)
  - Sustained back and leg pain relief with DTM™ SCS
  - Mean VAS scores were less than 2 at 12 months
- In terms of safety, the incidence of device-related adverse events and serious adverse events were consistent with other SCS studies.
- All DTM™ SCS RCT results were proven only on the Intellis™ stimulator.
Overview

Twelve-month results reporting on secondary outcomes related to quality of life in the DTM™ SCS RCT using the Medtronic Intellis™ SCS neurostimulator. Assessments included the Oswestry Disability Index (ODI), the PROMIS Scale v1.2-Global Health Score, Subject Satisfaction, and Patient Global Impression of Change (PGIC).

Effect on Disability (ODI)*

Clinically significant reduction in disability: DTM™ SCS increased from 27% of patients with moderate to minimal disability at baseline to 76% at 12 months.

Effect on Physical Health (PROMIS)*

Significant improvement in physical health: DTM™ SCS increased from 39% of patients experiencing excellent/very good/good/fair physical health at baseline to 88% at 12 months.

DTM™ SCS Subject Satisfaction*

83% of patients were satisfied or very satisfied with DTM™ SCS at 12-month follow-up visit.

DTM™ SCS Impression of Change*

84% of patients felt a great deal better/better or moderately better/somewhat better with DTM™ SCS at 12-month follow-up visit.

Key takeaways

- DTM™ SCS provided sustained improvements in degree of disability and quality of life at 12-month follow-up.
- SCS therapy improved subject ODI scores: Patients with DTM™ SCS went from 27% to 76% of subjects with minimal/moderate disability.
- SCS therapy improved subject ODI scores: Patients with DTM™ SCS went from 39% to 88% of subjects with excellent/very good/good/fair outcomes.
- The majority of subjects were very satisfied with SCS therapy: 62% of subjects with DTM™ SCS were Very Satisfied while 46% were Very Satisfied with Standard SCS.

Medtronic

Europe
Medtronic International Trading Sàrl.
Route du Molliau 31
Case postale
CH-1131 Tolochenaz
www.medtronic.eu
Tel: +41 (0)21 802 70 00
Fax: +41 (0)21 802 79 00

United Kingdom/Ireland
Medtronic Limited
Building 9,
Croxley Park,
Hatters Lane, Watford, WD18 8WW
United Kingdom
medtronic.com/covidien/uk
Tel: +44 (0)1923 212213
Fax: +44 (0)1923 241004

See the device manual for detailed information regarding the instructions for use, the implant procedure, indications, contraindications, warnings, precautions, and potential adverse events. For further information, contact your local Medtronic representative and/or consult the Medtronic website at www.medtronic.eu.

For applicable products, consult instructions for use on www.medtronic.com/manuals. Manuals can be viewed using a current version of any major internet browser. For best results, use Adobe Acrobat® Reader with the browser.

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