# Multicenter Randomized Clinical Trial to Assess the Effect of Active versus Passive recharge Burst Spinal Cord Stimulation on Pain Relief in Failed Back Surgery Syndrome

No registrations found.

| | |
|---|---|
| **Ethical review** | Not applicable |
| **Status** | Pending |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON27344

**Source**
Nationaal Trial Register

**Brief title**
BURST-RAP

**Health condition**

Failed back surgery syndrome, chronic low back pain

### Sponsors and support

**Primary sponsor:** Abbott Laboratories
**Source(s) of monetary or material Support:** Abbott Laboratories

### Intervention

### Outcome measures

**Primary outcome**

The primary endpoint is pain catastrophizing at 6 months after treatment started as measured with the pain catastrophizing scale

### Secondary outcome

• Pain intensity as measured with the 11-box NRS for 3 days, 3 times a day at baseline, directly after the trial and at 3 ,6 , and 12 months.
• Catastrophizing as measured with the pain catastrophizing scale (PCS) at baseline, 1 and 12 months.
• Attention to pain as measured with the Pain vigilance and Awareness Questionnaire (PVAQ) at baseline, and at 6, and 12 months after implantation of the system.
• Fear and Depression will be assessed using HADS- NL at baseline, 6 and 12 months.
• Quality of Life using the EQ-5D will be assessed at baseline and 6 and 12 months follow up
• Physical function assessed using the Oswestry Disability Index (ODI) at baseline, 6 and 12 months after implantation of the system
• Subject Satisfaction with treatment using the Patient Global Impression of Change (PGIC), a 7-point Likert scale at 1, 3, 6, and 12 months after implantation of the system.
• The number (percentage) of subjects who achieve a reduction in the LBP intensity of ≥50% and 30% within each system compared to baseline. Measured at 1 week (directly after the trial of the system), at 1 month, 3, 6, and 12 months.
• Pain intensity as measured with the 11-box NRS in other painful anatomy related to the back pain (e.g. Leg, buttock or foot) at baseline, and 1, 6, and 12 months after implantation of the system
• Chronic pain medication use will be collected at baseline and at all follow up timepoints. This includes opioids, analgesics, anticonvulsants, muscle relaxants, nonsteroidal anti-inflammatory drugs, and psychiatric mediation.
• Characterization of the pain will be assessed at baseline; at 1, 6 and 12month after implantation using the painDETECT® questionnaire (designed to differentiate neuropathic and non-neuropathic pain states). This may provide interesting data in post hoc analysis of responders and non-responders to the therapy
• In order to gain more insight into the role of charge delivery, in the light of pain relief and preference, Mean Charge per Second ‘CpS’ (µC/S) and Mean Charge per Hour ‘CpH’ (µC/h) will be documented, assessed and analyzed. In line with previous literature[28-30], the Mean Charge per Second/Hour will serve as an objective measure in order to elucidate the interplay and titration of parameters, within and between the stimulation modalities applied in this study.
• Safety will be monitored by the collection of events at each assessment point and reporting (as required) of device related adverse events (AE’s), device related serious adverse events (SAE’s) and any unanticipated SAE’s (regardless of device relatedness)

## Study description

### Background summary

Surgical lumbar discectomy is one of the most commonly performed routine spinal procedures, but this surgical intervention can lead to chronic post-surgical leg and/or back pain (failed back surgery syndrome, FBSS). Spinal cord stimulation has been shown to be effective for pain management in such patients. Patients receiving conventional tonic SCS (electrical pulses delivered in the 40-60Hz stimulation frequency range) experience paresthesia or a tingling sensation. Burst SCS is a newer paradigm that has been approved worldwide. Burst stimulation eliminates or greatly reduces the incidence of paresthesia. Two manufacturers currently employing variations of burst modalities are Abbott Laboratories and Boston Scientific. Abbot's burstDR employs passive recharge burst, while Boston's uses active recharge burst. It is still unknown if there are clinical differences between active recharge and passive recharge burst SCS. To date, no clinical studies have been performed that directly compared these two burst stimulation waveforms. Therefore, the objective of this RCT is to clinically compare passive recharge SCS with active recharge burst SCS. Based on the available scientific evidence the hypothesis is that the two systems are equal.

### Study objective

Based on the available scientific evidence the hypothesis is that the two systems are equal.

### Study design

Subject pain is assessed at baseline, following an initial implantation trial, at 1 month, 3 months, 6 months and 12 months.

### Intervention

Passive and active burst spinal cord neuromodulation.

## Contacts

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# Eligibility criteria

## Inclusion criteria

Subject of either gender between 18 and 65 years of age
• Al least moderate level of catastrophizing as measured with the Pain catastrophizing score (PCS) of at least 20.[23]
• History consistent with FBSS of at least 6 months
• Neurologic exam without marked motor deficit.
• Low Back Pain or leg pain intensity should be 5 or higher measured with the 11-box NRS 0-10
• Meets all the inclusion criteria for the implantation of a neurostimulation system as typically utilized in the study center. PM: depression is not an exclusion criteria
• Subject has been screened by a multi-disciplinary panel including a psychologist and deemed suitable for implantation
• Subject is able and willing to comply with the follow-up schedule and protocol
• Subject is able to provide written informed consent

## Exclusion criteria

Female subject of childbearing potential is pregnant/nursing or plans to become pregnant during the course of the study
• Escalating or changing pain condition within the past month as evidenced by investigator examination
• BMI ≥35
• Subject has had injection therapy or radiofrequency treatment for their low back pain within the past 3 months
• Subject currently has an active implantable device including ICD, pacemaker, spinal cord stimulator or intrathecal drug pump
• Subject is unable to operate the device
• Severe disc degeneration at the affected level as evidenced by >50% disc height loss on plain anteroposterior and lateral lumbar radiographs or CT/MRI.
• Moderate to severe spinal stenosis due to osteophyte and/or ligamentous overgrowth as evidenced by MRI or CT in the previous 6 months
• Moderate to severe endplate degenerative changes at the affected levels
• Grade 1-2 spondylolisthesis
• Previous Neurostimulation therapy

# Study design

### Design

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|---|---|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | N/A , unknown |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 01-12-2020 |
| Enrollment: | 96 |
| Type: | Anticipated |

### IPD sharing statement

**Plan to share IPD:** Undecided

## Ethics review

Not applicable

| | |
|---|---|
| Application type: | Not applicable |

## Study registrations

### Followed up by the following (possibly more current) registration

ID: 52034
Bron: ToetsingOnline
Titel:

### Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

| Register | ID |
|---|---|
| NTR-new | NL9194 |
| CCMO | NL75451.091.20 |
| OMON | NL-OMON52034 |

# Study results