Reviewer's report

Title: Comparison of tonic spinal cord stimulation and high-frequency and burst stimulation in patients with complex regional pain syndrome: a double-blind, randomised placebo controlled trial

Version: 1 Date: 6 February 2015

Reviewer: Elon E Eisenberg

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Comments to protocol:

“Comparison of tonic spinal cord stimulation and high-frequency and burst stimulation in patients with complex regional pain syndrome: a double-blind, randomized, placebo controlled trial.

Overall, it is an interesting study with appropriate rational and suitable methodology.

Several comments:

1. Sample size: given the fact that three primary outcomes were selected, I wonder if a correction for multiple comparisons (such as Bonferroni or similar) has been taken into account.

2. While appreciating the fact that during the initial trial, 40 Hz stimulation is the standard of care, I wonder if at least for at least short durations (perhaps one day at the time or so) other frequencies could be tested as well. This will allow patients who do not respond to the standard stimulation not to have their electrodes pulled out and give them a chance to benefit from SCS after all. This is an ethical consideration.

3. It might be reasonable to consider not no include a 40Hz stimulation in the statistical analysis, given the bias which arises from the initial stimulation period.

4. Please provide information on the randomization (computerized? blocks?)

5. Please provide clear information on the intensity of the stimulation in each treatment period. Is it going to be sub-threshold for all treatments? only for the burst stimulation? Please also give the rational for your decision.

6. Please provide the parameters for the burst stimulation.