

Subcutaneous Injection of Botulinum Toxin A for At-Level Back Pain in Patients  
with Spinal Cord Injury

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NCT02736890

Document Date: 12/29/2015

"Data analysis plan:

The primary outcome measure used to determine treatment effect in this study was patient reported average pain intensity over the prior week. This measure is part of the International SCI Pain Basic Data Set (ISCIPBDS), whose validity and utility in individuals with SCI has been demonstrated, and is also among the measures recommended for use in SCI clinical trials. Subjects were asked to rate their average pain using the 0-10 NPRS with endpoints of 0 ("no pain") to 10 ("worst pain imaginable"). Secondary outcome measures included other items from the ISCIPBDS such as the degree to which pain interfered with: (1) day to day activities, (2) mood, and (3) sleep, all on 0-10 numeric scales with endpoints of 0 ("no interference") to 10 ("extreme interference"). At each follow-up time point, subjects were also asked to quantify the change in quality of life appreciated after injections on a 0-6 numeric scale based on the Patient Global Impression of Change (PGIC) scale. Our adaptation of this scale had endpoints of 0 ("no change, or condition got worse") to 6 ("a great deal better, a considerable improvement that has made all the difference"). Lastly, subjects were asked about and monitored for any AEs.

All collected research data were stored in a password-protected REDCap database and all hard copy forms were kept in locked files in the offices of research staff. Statistical analyses were performed using SPSS version 22.0. Power analyses were conducted based on the primary outcome of change in pain intensity on the NPRS from baseline. We determined that a minimal clinical important difference (MCID) on the NPRS would be  $\geq 3$  points on the 0-10 point scale, that 30% of participants in the placebo group would have a positive response to treatment, and that 40% more participants (i.e. 70%) would respond in the treatment group. Assuming a two-sided alpha of 0.05, a sample size of 28 would have provided 86% power that a difference will be found. Assuming a 15% drop out rate, a sample size of 32 enrolled participants was deemed necessary for sufficient power to detect treatment effect. Our study failed to meet this target sample size and it was ultimately determined that our findings would be best presented as a descriptive case series."