

A Novel Radiosurgical Treatment for Spasticity: Preliminary Results from a Sham-Controlled Prospective Trial

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Pantaleo Romanelli ¹, Evan Thomas ²

1. Neurosurgery, Cyberknife Center, Centro Diagnostico Italiano, Milano, ITA 2. Radiation Oncology, Ohio State University, Columbus, USA

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Abstract

Objectives:

Frameless LINAC radiosurgery directed to the sensory region of selected nerve roots has been recently described as a novel treatment option to relieve severe spasticity. A prospective Sham-Controlled Trial of Dorsal Root Rhizotomy Stereotactic Radiosurgery versus Standard of Care for Spasticity Associated with Stroke, Spinal Cord Injury and Cerebral Palsy is currently underway to provide a solid assessment about the efficacy and safety of this novel treatment.

Methods:

Patients with motor plegia (from stroke, spinal-cord injury, or cerebral palsy) and severe chronic spasticity (MAS ≥ 4) will be randomized in a single-blinded, 1:1 fashion to SRS dorsal root rhizotomy at the anatomically appropriate (and NCV/EMG verified) levels versus sham treatment. SRS will be delivered via linear accelerator with a prescription dose of 50Gy to the margin of the dorsal root target. Patients will be assessed at 1, 3, 6, 12, and 24 month timepoints after treatment. The primary outcome by which the hypothesis is to be tested is a measure of the reduction in a patient's spasticity score on the Modified Ashworth Scale of 2 or more levels at 6 months preceding treatment. Secondary outcomes include patient quality of life measures and toxicity according to CTCv5.0 and SQoL-6D) as well as changes in NCV/EMG values of the treated anatomic regions. Sham patients have a crossover option at 6 months.

Results:

A randomized sham-controlled trial has been approved and funded to investigate whether stereotactic irradiation delivering 50 Gy to the sensory region of selected spinal nerve roots is beneficial in the treatment of severe spasticity. Up to 60 patients can be studied. Details of the trial are available at <https://clinicaltrials.gov/search?cond=spasticity&intr=Stereotactic%20Radiosurgery>. Preliminary results on 7 patients undergoing stereotactic irradiation of the sensory region of selected spinal roots have already shown that this technique is well tolerated, free of complications and highly effective to relieve spasticity and related pain.

Conclusion(s):

Preliminary results support the notion that stereotactic irradiation of the sensory region of selected spinal roots generates substantial improvement of spasticity and related-pain. This technique appears to be well tolerated, free of complications and highly effective to relieve spasticity and pain. The ongoing randomized trial will add crucial data to assess the real potential of this novel technique, which appears to have the full potential to become a disruptive innovation.