Title: **Safety of Granulocyte Colony-Stimulating Factor Administration for Non-traumatic Spinal cord Myelopathies: An Open-Label, Phase I Study**

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Abstract:

Objective: Granulocyte-colony stimulating factor (G-CSF) is a major growth factor for activation and differentiation of granulocyte colonies in the bone marrow. This cytokine has been widely and safely employed in different conditions such as traumatic spinal cord injuries over many years. The purpose of this translational study was to investigate the safety of G-CSF administration for non-traumatic spinal cord myelopathies (non-TSCMs).

Methods: This phase I, safety clinical trial was performed in 5 patients with incomplete non-TSCMs, with American Spinal Injury Association Impairment Scale (AIS) grades B or C were enrolled. All cases had either Pre- or Post-operative neurological deterioration in upper cervical spinal cord due to disc herniation or intramedullary tumors.

Patients were assessed using the International Standards for Neurological Classification of Spinal Cord Injury (ISNCSCI) scale and AIS, just before intervention and at 1, 3, and 6 months, after 7 daily subcutaneous administrations of 300 µg/day of G-CSF during the first week after surgery. Also reported side effects of the G-CSF were evaluated.

Results: After 6 months of follow-up, 2 patients with cervical disc herniation and cervical canal stenosis improved from AIS grade C to grade D. One 33 years old female patient with ependymoma tumor lesion, improved from AIS grade B to grade C, and achieved spontaneous breathing. Also, a 31 years old male patient with meduloblastoma within the obex showed improvement. A case with thoracic cavernous hemangioma showed evidence of improvement. All cases showed mild side effects of the G-CSF treatment such as bone and muscle pains or fever. All of them were transient and subsided spontaneously within 1 week after the last dose of G-CSF.

Conclusions: Our results indicate that G-CSF administration is a safe process and is associated with possible neurological improvement in non-TSCMs.