Interim Report Of Double Blind Randomized Clinical Trial On G-CSF Administration For Subacute Traumatic Spinal Cord Injuries, Safety And Efficacy

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Purpose:
In this study we tried to determine the safety and efficacy of G-CSF administration for neurological and functional changes in sub-acute incomplete traumatic spinal injuries (TSCI).

Methods:
This phase II/III, prospective, double-blind, placebo-controlled, Randomized Clinical Trial was performed on sixty eligible TSCI cases. Patients were assessed by ASIA, Spinal Cord Independence Measure (SCIM-III) and IANR-SCIFRS, just before intervention and at 1, 3 and 6 months, after seven daily subcutaneous administrations of 300 µg/day of Granulocyte Colony Stimulating Factor (G-CSF) in the treatment group, and placebo in the control group.

Results:
After 6 months of follow up, AIS grade remained unchanged in the placebo group, while in the G-CSF group 5 cases (45.5%) improved from AIS B to C, five (45.5%) AIS C patients improved to AIS D, and 1 case (16.7%) improved from AIS D to E. The mean (±SE) change in ASIA motor score in the G-CSF group was significantly more than the placebo group ($P<0.001$). The mean (±SE) light touch and pinprick sensory points, improved significantly in the G-CSF group, in comparison to the placebo group, ($P=0.005$ and, 0.002 respectively). Evaluation of functional changes by IANR-SCIFRS instrument revealed significantly more functional improvement in G-CSF group, in comparison to the placebo group, ($P <0.001$). Also significant difference was observed between the two groups as measured by SCIM-III instrument ($P <0.001$).

Conclusions:
Incomplete subacute TSCI patients may safely receive GCSF after surgery (decompression and fixation). Also statistically significant motor, sensory, and functional improvement happensfollowing G-CSF administration.