Systemic Cell Therapy using human mononuclear cord blood cells (hUCBCs) in patients with Acute Severe Contusion Spinal Cord Injury (ASIA A, B): Phases I/IIa of randomized open-label safety and primary efficiency clinical study

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Introduction: Spinal Cord Injury (SCI) is a severe injury of CNS resulting in disability and a significant decrease in quality of life. The uncomplicated injury of the spine is easily and effectively treated in almost all cases using current surgical techniques, but no effective treatment of SCI is currently available. We published earlier the results of a preclinical study series using human mononuclear UCBCs in animal models of SCI. These studies demonstrated the high efficiency of systemic cell therapy resulted in regression of motor deficit up to 53% compared to placebo and decrease in myelopathy area volume according to 7,0 Tl MRI examination.

Materials and Methods: Phases I/IIa randomized open-label clinical study of cell therapy safety and primary efficiency in patients with acute contusion SCI and ASIA A/B neurological deficit was carried out. 20 patients were included in the study divided into 2 groups. Treated patients obtained 4 IV infusions of 300 x 106 mononuclear hUCBCs weekly. The follow-up period reached 1 year.

Results: The performed study was approved by Institutional Review Board and registered in the ClinicalTrials.gov portal. Safety evaluation was carried out using CTCAE v5.0 classification. The overall amount of 392 adverse events was registered in 20 patients. Only 2 of them were likely to be related to cell therapy, both were moderate. No other side effects or complications related to cell therapy were detected in all patients. No signs of immunization were observed. The conducted efficiency analysis demonstrated restoration of spinal cord functions and improvement of outcomes compared to routine therapy. The mean increase of the ASIA scale in the experimental group reached 2.2 while in the control group it was 0.9. The total index of motor scale in upper extremities (UEMS) and lower extremities (LEMS) in the treated group reached 77 ± 19 points while in the control group it was 33 ± 21.6. 78% of treated patients were able to stand and walk autonomously while in the control group only 30% were able to perform that. Cell therapy also decreased the spasticity level in lower extremities assessed by the modified Ashworth scale and promoted the improvement in self-urination ability in patients with neurological urinary retention. Quality of life was also significantly higher in the cell therapy group according to the FIM scale.

Conclusion: Thus systemic cell therapy utilizing mononuclear human UCBCs is a safe and effective method of regenerative therapy on acute contusion SCI.

Biography

Vladimir A Smirnov is specialized in Orthopedic Surgery and Spine Neurosurgery, completed PhD in 2019 at the age of 31 from Sklifosovsky Emergency Care Institute, Moscow, Russia by the topic of "Systemic application of mononuclear cord blood cells for the treatment of severe spinal cord contusion in an animal model". He has completed the series of experimental studies using cord blood stem cells in an animal model of spinal cord injury. In 2015-2018 Vladimir A Smirnov completed I/IIa phases of clinical studies in patients with severe Spinal Cord Injury. He has published more than 17 papers in reputed Russian and foreign journals.

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