TITLE: Intrathecal Autologous Bone Marrow Derived Mesenchymal Stem Cell Injection for Ischemic Stroke: Safety and Short Term Efficacy Study.

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ABSTRACT:

Background: Preclinical and animal studies provide considerable hope for stem cell therapy in cerebrovascular stroke. This study was designed as a pilot study to explore this provisional data. Autologous bone marrow derived mesenchymal stem cells were chosen due to their proven angiogenic, paracrine and neuroregenerative functions. Subjects and Methods: The present study included 32 patients with ischemic stroke fulfilling the following criteria: Inclusion Criteria: 1. Patients with established stroke in the distribution of the middle cerebral artery territory. 2. Six months at least after the onset of acute ischemic stroke. 3. CT brain at the onset denoting acute ischemic stroke. Exclusion Criteria: 1. Hemorrhagic stroke. 2. Conditions which mimick stroke, e.g., multiple sclerosis, vasculitis, arteriovenous malformations, trauma, tumours. Patients were randomly divided into control group (11 patients) and study group (21 patients) which was further divided according to the time between the onset of the stroke and the beginning of the study into: Group I: onset of the stroke and the beginning of the study :6-12 months( 12 patients: 6 males and 6 females). Group II: onset of stroke and the beginning of the study :13-36 months (9 patients: 5 males and 4 females).

Control Group: 11 stroke patients: 6 males and 5 females. Time from onset of stroke to beginning of the study ranged from 6-30 months. Both study and control group were subjected to thorough clinical and laboratory assessment, CT brain, National institutes of Health Stroke Scale (NIHSS) and th Barthel active daily life (ADL) scale at the start of therapy, and at 1,3,6 and 12 months after the start of therapy. Stem Cell Injection: 10 million autologous bone marrow-derived MSCs were injected via lumbar puncture in the study group. Results and Conclusions: Changes in Follow-up Parameters: 1. Changes in NIHSS score: Control group showed non-significant decrease in NIHSS score starting from the 3rd month. On the other hand, study group showed highly significant decrease in NIHSS score starting from 6th month, more in group I. 2. Changes in ADL score: ADL score showed non-significant increase starting from 3rd month in the control group, while it showed a highly significant increase in the study group starting from 6th month, more pronounced in group I. Intrathecal administration of MSCs is safe and enhances regeneration in ischemic stroke patients.

Keywords: Mesenchymal Stem Cells, Stem Cell Therapy, Ischemic Stroke, Neuroregeneration