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Retrospective Study

Phase I study on the safety and preliminary efficacy of allogeneic mesenchymal stem cells in hypoxic-ischemic encephalopathy

Serdar Kabataş, Erdinç Civelek, Necati Kaplan, Eyüp Can Savrunlu, Gülseli Berivan Sezen, Mourat Chasan, Halil Can, Ali Genç, Yener Akyuva, Osman Boyalı, Furkan Diren, Erdal Karaoz

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The current study examined **safety and preliminary efficacy** estimates of intravenous **allogeneic mesenchymal stem cells** in this population. Methods- Entry criteria included **ischemic stroke** >6 months prior and substantial impairment (National Institutes of Health Stroke Scale score ≥ 6) and disability.

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This was a phase I/II multi-center, open-label study that aimed to evaluate the **safety and preliminary efficacy** of a single intravenous infusion of marrow-derived allogeneic ischemia-tolerant MSC. Entry criteria appear in Table 1 and in sum describe enrollment of adults with radiologically verified **chronic stable ischemic stroke** and substantial impairment and functional deficits.

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Phase I/II Study of Safety and Preliminary Efficacy of Intravenous Allogeneic Mesenchymal Stem Cells in Chronic Stroke Michael L. Levy, MD, PhD; John R. Crawford, MD; Nabil Dib, MD; Lev Verkh, PhD; Nikolai Tankovich, MD, PhD; Steven C. Cramer, MD Background and Purpose—Stroke is a leading cause of long-term disability. Limited treatment options exist

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Levy ML, Crawford JR, Dib N, Verkh L, Tankovich N, Cramer SC. **Phase I/II Study of Safety and Preliminary Efficacy** of Intravenous **Allogeneic Mesenchymal Stem Cells** in Chronic Stroke. Stroke. 2019 Oct;50(10):2835-2841. doi: 10.1161/STROKEAHA.119.026318. Epub 2019 Sep 9.

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