

## **Retrospective Chart Review Study of Human Umbilical Cord Blood Derived Mesenchymal Stem Cell Therapy in Subjects with Stroke**

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**The Purpose of the Study:** The current study is a case-control, retrospective analysis of mobility and muscle strength of upper and lower extremities, and neurological function pre and post therapy in Stroke patients treated with either Human umbilical cord blood-derived mesenchymal stem cells, or conventional therapy.

### **Background:**

Stroke is a leading cause of adult disability worldwide and the second highest cause of death in the world [1]. 70–85% of first strokes are accompanied by hemiplegia. Six months after stroke, only 60% of people with hemiparesis who need inpatient rehabilitation have achieved functional independence in simple activities of daily living. Patients with sensorimotor and visual-field loss are much more dependent on carers than those with pure motor impairments, but even the latter

may walk too slowly to participate in out-of-home activities or may be unable to integrate the use of an affected arm into personal care [2]. Despite decades of research, no clinically effective pharmacotherapies exist which can target both ischemia and reperfusion injury as well as facilitate cellular functional recovery after an ischemic stroke [3]. The advent of stem cell therapy presents an exciting new frontier for research in stroke treatment. In addition to preventing the ongoing damage, which has been the focus of conventional therapy, stem cell transplantation actually repairs the injured brain. It has emerged as a potential regenerative treatment to reduce post-stroke handicap [4, 5]. Over the past decade the use of mesenchymal stromal cells (MSCs) as therapy has emerged as a particularly attractive option. MSCs are a class of multipotent, self-renewing cells that give rise to differentiated progeny when implanted into appropriate tissues [6]. Human umbilical cord blood-derived mesenchymal stem cells (hUCBSC) are adult stem cells and a promising candidate for cell-based therapy [10]. The advantages of hUCBSC administration include painless collection procedure, faster self-renewal, ability to differentiate into three germ layers, accumulation in damaged tissue or inflamed regions, induction of tissue repair, and modulation of immune response [7-10]. The transplantation of MSCs influences a wide range of events by modulating the inflammatory environment, stimulating endogenous neurogenesis and angiogenesis and reducing the formation of glial scar, although the precise, underlying mechanism of this phenomenon remains unknown [11]. Although MSC therapy after Stroke has shown promising results, only a limited number of studies has been conducted this far. Further research is required for better characterization of the safety and efficacy of stem cell therapy for Stroke.

Fifty patients with Sequelae of cerebrovascular hemorrhage and CVA (Stroke) Sequelae will be randomly selected from 96 patients treated with hUCBSCs at the Wuhan Hongqiao Brain

Hospital Co., Ltd. (Wuhan, Hubei) between March 2009 and March 2012. Another fifty patients with Stroke, who received only traditional therapy and no stem cell therapy, will be included as the control group.

Chart records are located at the Wuhan Hongqiao Brain Hospital Co., Ltd. (Wuhan, Hubei) and Mehling Orthopedics (214 State Street, Hackensack, NJ 07601) and will be utilized from Mehling Orthopedics (214 State Street, Hackensack, NJ 07601).

Data collection will include: base-line characteristics of research subjects, adverse events specification after therapy, physical examination results pre- and post-therapy, including mobility of upper and lower extremities, neurological function, and muscle strength of upper and lower limbs.

Each patient will have study number. No names will be listed in our study. Information will be stored the same way as medical charts are stored according to HIPPA compliances.

Potential benefits are improvement of understanding of stem cells therapy for stroke.

Data analysis will include analysis of mobility, muscle strength of upper and lower extremities and neurological function pre- and post-therapy in stem cell and conventional therapy group; correlation between initiation of stem cell treatment and effectivity of treatment; correlation between stem cell infusion/injection strategy and effectivity of treatment.

## **References**

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