

## **Evidence-based of human MSC cell therapy**

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### **Abstract**

Stroke is a result of cerebral ischemia that triggers a cascade of both physiological and biochemical events. Stem-cell-based therapies represent a new possible strategy for stroke clinical research. The objectives of this Phase I clinical study were to assess the feasibility and toxicity of GXNPC1 (a stem cell preparation) intracerebral transplantation and to test the impact of GXNPC1 in chronic stroke patients. The trial was approved and monitored by Taiwan Food and Drug Administration (NCT02813512). The site of this clinical trial is in Hualien Tzu Chi Hospital. GXNPC1 were isolated from patient's autologous adipose tissue, expanded in vitro and analyzed according to GMP conditions (Gwo Xi Co., Ltd.). After collecting, GXNPC1 were suspended in 1 ml physiological saline and intracerebral transplanted with a stereotactic brain surgery. Three patients will enroll and regularly monitored by clinical and psychological assessments before and after intracerebral transplantation in one, third and sixth months. This Phase I study was conducted to demonstrate the safety and efficacy of administering GXNPC1 to three subjects with chronic stroke. An analysis of adverse drug reactions and suspected/unexpected severe adverse reactions revealed no safety issues with respect to administering GXNPC1 to patients, and treatment resulted in a tendency for improvements in the National Institutes of Health Stroke Scale, Barthel Index, Berg balance scale, Fugl-Meyer assessment, and somatosensory evoked potentials. In conclusion, this clinical study suggested that the intracerebral transplantation of GXNPC1 is safe and that might have a clinical use for future chronic stroke cell based clinical trials.