Two years results of phase I clinical trial for chronic stroke patients treated with autogenous CD 34+ stem cells transplantation and preliminary results of phase II study
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使用自體幹細胞治療慢性中風病患第一期臨床試驗兩年結果報告及第二期結果報告
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Purpose
There are no effective and aggressive methods for chronic stroke patients. Stem cell therapy rising promising hope in many neurological diseases. We try to transplant autogenous CD 34+ stem cell into chronic stroke patients and test their effects and safety.

Materials and Methods
From Aug. 2006 to Jun. 2007 there were seven chronic stroke male received the transplantation. One patient found terminal oral cancer two months after operation and he was excluded from the study. All the patients received subcutaneous granulocyte colony stimulation factor (G-CSF) injection for five days. Then blood electrophoresis performed on the sixth days and CD34+ stem cell were extracted at GMP lab in the same day. Stereotactic transplantation procedures were performed in the same day evening. All the patients received imagine study (MRI, FDG-PET, Brain perfusion) and functional assessment (NIH stroke scale, European stroke scale, BARTHEL scale, Mini – Mental state examination, European motor scale, Gait analyzer, Balance test) pre and post operation regularly as schedule.
The phase II clinical began Aug 2009 and scheduled fifteen transplant patients with the same number control patients with comparison.

Results
1. Total six patients age from 46 to 70 years old (55.5±8.8) were included.
2. Every patient received 3-8 x 10^6 (6.2 ± 1.9 x 10^6) CD34 stem cell
3. The second patient developed subdural effusion and the fourth patient suffered from stitch reaction. Others did not have major complications
4. The primary endpoint (NIHSS, ESS, EMS and BI) got 65% improvement in three patients and 30% improvement in other three patients
5. In the secondary end point (FDG-PET and TMS), in FDG-PET showed activated neuronal activities in peri-infarction areas. The TMS showed
reappearance of neuronal electricity in lesion limbs
6. Regeneration of the cortical spinal tract were found in some patients

Conclusion
1. There is no major complication after the operation in these seven patients.
2. The two years follow up results showed improved neurological functions and cerebral blood flow in ischemic areas
3. Younger patients had better improvement rate than older patients
4. The stereotactic transplantation is a minor surgical procedure and its complication rate is low with good training and planning.
5. Phase II study including operation and control groups with larger number size could provide more results that will be benefit to future cell therapy.