CHINASCINET
中國脊髓損傷研究協作組

Press Release

First Clinical Trial of Combination Therapy of Umbilical Cord Blood Cell and Drugs for Spinal Cord Injury

Spinal cord injury (SCI) is usually caused by a sudden trauma to the vertebral column which compresses and damages the spinal cord. The injury to the spinal cord disconnects the motor and sensory connections between the brain and the rest of the body. This causes sensory loss, neuropathic pain, and lifetime paralysis. The resulting condition is a dreadful burden for patient and family. The most common causes are traffic accidents, falls and sport injuries. Every year approximately 78,000 people in China suffer from SCI. According to the Department of Health, 452 patients with the injury were recorded in Hong Kong in 2000.

SCI has long been considered an irreversible condition, but advances in science in the last decade are changing this perception. Recent studies showed that umbilical cord blood cells transplanted into the spinal cord of animal can improve the function of spinally-injured animals. Umbilical cord blood cells have long been transplanted safely into thousands of people. The cord blood cells can be human leukocyte antigens (HLA) matched to prevent immune rejection and the cells are well-behaved after transplant which do not grow into tumors. Methylprednisolone may increase the survival of transplanted cells and lithium stimulates the cells to produce growth factors which stimulate regeneration in the spinal cord.

In 2010, China Spinal Cord Injury Network (ChinaSCINet) in collaboration with The University of Hong Kong (HKU) and The Chinese University of Hong Kong (CUHK) has initiated the first clinical trial of combination therapy of human umbilical cord blood mononuclear cells (hUCBMCs) transplant and oral lithium to treat chronic SCI. The primary objective of this Phase II study is to assess the safety and feasibility of the combination therapy in patients with complete spinal cord injuries and stable neurological function. Participants in the study are being assigned to different treatment groups to receive 1.6 million to 6.4 million hUCBMCs treatment with and without combinations of methylprednisolone and oral lithium.

The HLA-matched human cord blood cells are being donated by Stemcyte Inc., a US cord blood bank. The mononuclear cells which include CD34+ and CD133+ stem cells are isolated and purified in a highly-certified laboratory in US and shipped to Hong Kong for the treatments.

By the end of March 2011, a total of six patients have received hUCBMCs therapy from the clinical teams lead by Prof. Wai-sang Poon from the Chinese University of Hong Kong and Dr. Gilberto Leung from The University of Hong Kong. The participants will

be followed for one year to assess the safety and treatment effect of the cell therapy.

“We are pleased to participate in this advanced cell therapy study,” said Dr. Gilberto Leung, Neurosurgeon, and Clinical Assistant Professor of the Department of Surgery, The University of Hong Kong “The patient will be closely monitored after the therapy to evaluate changes of neurological function.”

Prof. Poon Wai-sang, Chief of the Division of Neurosurgery, Department of Surgery, the Chinese University of Hong Kong, said “This clinical trial marks the involvement of the medical community in Hong Kong in finding a cure for spinal cord injury, a condition long regarded to be incurable.”

“ChinaSCINet with the mission to bring the most promising therapies to clinical trials for SCI, is proud to coordinate the trial and to collaborate with two respected universities in Hong Kong to test the therapy.” said Prof. So Kwok-fai, Co-Chairman of the Board of Directors, ChinaSCINet and Head of the Department of Anatomy, The University of Hong Kong.

“Initiating the combination therapy clinical trial is a milestone for spinal cord injury. Based on the results of this Phase II trial, ChinaSCINet will design a Phase III multicenter trial in Mainland China, Taiwan and Hong Kong to evaluate the efficacy of the hUCBMCs therapy.” Prof. Wise Young, Co-Chairman of the Board of Directors, ChinaSCINet and Professor at the Rutgers, The State University of New Jersey satatesthat “ChinaSCINet is a platform to accelerate the development and availability of therapies that improve the function in people with SCI.”

The trial is currently open for SCI patient recruitment. Further information on the clinical trial and the criteria for patient eligibility for the study is available on the NIH clinical trial registry ClinicalTrials.gov with title “*Safety and Feasibility of Umbilical Cord Blood Cell Transplant into Injured Spinal Cord: an Open-Labeled, Dose-Escalating Clinical Trial*".

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