

Clinical Trial CN102B Information

The clinical trial CN102B "Safety and Feasibility of Umbilical Cord Blood Cell Transplant into Injured Spinal Cord: an Open-Labeled, Dose-Escalating Clinical Trial" is now open for subject recruitment. Dr Gilbert Leung and Dr Yat-wa Wong from The University of Hong Kong (HKU), Prof. Wai-sang Poon from The Chinese University of Hong Kong (CUHK), and Prof. Wise Young from ChinaSCINet and The State University of New Jersey (Rutgers, USA) are the principle investigators of the trial. This trial is planned to start in early March 2010.

The trial details have been posted on <http://clinicaltrials.gov/ct2/show/NCT01046786>. Briefly, the trial will recruit 20 subjects with chronic traumatic spinal cord injury at C5 and T10 levels inclusive (more than one year after injury with stable neurological function); who are classified on the ASIA Impairment Scale as A ("complete" spinal cord injury); who do not have significant contraindications to the surgery, methylprednisolone or lithium; and for whom we can find an umbilical cord blood unit that matches at least 4:6 human leukocyte antigens (HLA) -A, -B, and -DR. The institutional review boards (IRB) of HKU and CUHK, and Hong Kong Department of Health have approved the trial.

The subjects will be randomized into five treatment groups and four subjects for each group. The first three groups will receive respectively 4, 8, and 16µliters of 100,000 HLA-matched mononuclear cells/µliter. Cells will be transplanted by four injections 3mm-deep into dorsal root entry zones of spinal cord above and below the injury site. The fourth group will receive the highest safe transplant volume plus an intravenous bolus of 30 mg/kg methylprednisolone to improve the survival of transplanted cells. The fifth group will receive the transplant, methylprednisolone, and a 6-week course of oral lithium carbonate titrated to serum levels of 0.6 to 1.0 mM. Lithium stimulates the cell growth, produces growth factors and hence stimulates regeneration.

StemCyte, a US cord blood bank, will donate the HLA-matched human umbilical cord blood cells. The units have been tested extensively to rule out diseases. A highly-certified U.S. laboratory (Vista Biologicals) will thaw, isolate, and purify mononuclear cells from the units. These cells include CD34+ and CD133+ stem cells in umbilical cord blood. The cells will be shipped from the United States to Hong Kong without culturing or growing of the cells. Stemcyte units are certified by National Marrow Donor Program criteria for safety of transplantation to treat other conditions.

The surgical operation will be performed by Prof. Wai-sang Poon from Prince of Wales Hospital (The Chinese University of Hong Kong) and Dr. Gilbert Leung from Queen Mary Hospital (The Hong Kong University). The hospitalisation period will be within the discretion of the principal investigators which is probably be one week. Rehabilitation will be voluntary after transplantation. Follow-up assessment will be performed at second-week, six-week, six-month, and twelve-month after transplantation. Some of the assessments will be conducted at the MacLehose Rehabilitation Centre.

The trial aims to assess the feasibility and safety of transplanting umbilical cord blood

cells into the spinal cord in subjects with chronic spinal cord injury. During transplantation, the injection may cause local damage to the spinal cord. Such damage is unlikely at the small volumes (4-16 μ liters) that will be injected. In China, patients routinely get more than 35 μ liter cell injections into spinal cord without neurological loss. Cell transplants may cause inflammation or meningitis but this is unlikely because the cells are extensively tested to rule out infectious disease and are HLA-matched to reduce the likelihood of immune rejection. During the first week after transplantation, the subjects will be closely monitored in hospital for neurological changes and adverse effects. After discharged, neurological function will be closely monitored at six-week, six-month and twelve-month after implantation to monitor the performance progress.

The trial is based on data from multiple animal studies indicating that umbilical cord blood mononuclear cells (UCBMC) transplanted into spinal cord are well-tolerated can improve function in animals after spinal cord injury. Methylprednisolone may increase the survival of transplanted cells and lithium stimulates umbilical cord blood mononuclear cells to produce growth factors (neurotrophins) that stimulate regeneration in the spinal cord. Based on the results of this phase I/II trial, a phase III trial will be decided and planned to evaluate the efficacy of umbilical cord blood mononuclear cells with and without methylprednisolone and lithium.

If you are interested in participating in this trial or you have any enquiries, please feel free to contact us for further information:

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