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Trial record **1 of 1** for: umbilical cord blood and parkinson disease

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Umbilical Cord Derived Mesenchymal Stem Cells Therapy in Hypoxic Ischemic Encephalopathy

This study is currently recruiting participants.

Verified September 2013 by Hebei Medical University

Sponsor:
Hebei Medical University

Information provided by (Responsible Party):
Quanhai Li, Hebei Medical University

ClinicalTrials.gov Identifier:
NCT01962233

First received: September 11, 2013
Last updated: October 10, 2013
Last verified: September 2013
History of Changes

Full Text View | Tabular View | No Study Results Posted | Disclaimer | How to Read a Study Record

Purpose

This study is to evaluate the safety and efficacy of **Umbilical Cord** Derived Mesenchymal Stem Cells transplantation in hypoxic ischemic encephalopathy.

Condition	Intervention	Phase
Hypoxic Ischemic Encephalopathy	Biological: mesenchymal stem cells	Phase 1

Study Type: Interventional
Study Design: Endpoint Classification: Safety/Efficacy Study
Intervention Model: Single Group Assignment
Masking: Open Label
Primary Purpose: Treatment

Official Title: Safety and Efficacy Investigation of Patients With Hypoxic Ischemic Encephalopathy by Transplantation of **Umbilical Cord** Derived Mesenchymal Stem Cells

Further study details as provided by Hebei Medical University:

Primary Outcome Measures:

- National Institutes of Health Stroke Scale (NIHSS) scores. [Time Frame: 180 days] [Designated as safety issue: No]

  The NIHSS is a systematic assessment tool that provides a quantitative measure of stroke-related neurologic deficit. Values range from 0 (no deficit) to 42 (dead).

Secondary Outcome Measures:

- The Barthel Index [Time Frame: before treatment and post cell transplantation:15,90,180 days] [Designated as safety issue: No]

  The Barthel Index measures 10 activities of daily living and mobility. A score of 100 is best (able to live at home with a degree of independence), 0 is worst.

- The Mini-Mental State Examination (MMSE) [Time Frame: before treatment and post cell transplantation:15,90,180 days] [Designated as safety issue: No]

  The Mini-Mental State Examination (MMSE) is a screening test for cognitive dysfunction. The test consists of five sections (orientation, registration, attention-calculation, recall, and language); the total score can range from 0 to 30, with a higher score indicating better function.

- The Montreal Cognitive Assessment(MoCA) [Time Frame: before treatment and post cell transplantation:15,90,180 days]

[Designated as safety issue: No]

The Montreal Cognitive Assessment(MoCA) is a brief 30-point screening instrument that was developed and validated to identify subjects with mild cognitive impairment. 30 is the maximum score, with a score of 26 or higher considered normal and below 26 indicative of Mild Cognitive Impairment.

- Unified **Parkinson's Disease** Rating Scale (UPDRS) [Time Frame: before treatment and post cell transplantation:15,90,180 days.] [Designated as safety issue: No]

  The UPDRS score has 4 components. Part I assesses mentation; Part II assesses activities of daily living; Part III assesses motor abilities; Part IV assesses complications of therapy. A total of 44 items are included in Parts I-III. Each item will receive a score ranging from 0 to 4 where 0 represents the absence of impairment and 4 represents the highest degree of impairment. Part IV contains 11 items, 4 of these items are scored 0-4 in the same manner, and 7 are scored 0-1, with 0 indicating the absence of impairment and 1 indicating the presence of impairment. Total UPDRS score represents the sum of these items in Parts I-IV. A total of 199 points are possible. 199 represents the worst (total) disability), 0--no disability.

- adverse reaction [Time Frame: post cell transplantation:15,90,180 days] [Designated as safety issue: Yes]

  adverse reaction include temperature changes,the change of blood pressure,anaphylaxis,seizure,renal dysfunction,or hepatic injury by monitoring blood routine, urinalysis, ALT,AST,Urea,Crea and electrocardiogram etc.

Estimated Enrollment:	10
Study Start Date:	September 2013
Estimated Study Completion Date:	December 2014
Estimated Primary Completion Date:	December 2013 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: mesenchymal stem cells **Umbilical Cord** Derived Mesenchymal Stem Cells at a dose of 100-800 million by intravenous infusion	Biological: mesenchymal stem cells Procedure: On the basis of conventional therapy, at the same time, selected patients were given by intravenous infusion of **umbilical cord blood** stem cells 100-800 million. All patients before treatment, after treatment for 15days, 90days and 180 days were evaluated respectively the curative effect. Intravenous infusion of **umbilical cord** derived mesenchymal stem cells

Detailed Description:

To date,hypoxic ischemic encephalopathy is refractory, including after carbon monoxide poisoning, cardiopulmonary resuscitation,hemorrhagic shock and cerebral infarction etc. We used Mesenchymal Stem Cells via portal vein infusion method to treat hypoxic ischemic encephalopathy. With different durations of follow-up, we cleared therapeutic effect, the quality of life and prognostic implications of the cord blood stem cell infusion on hypoxic ischemic encephalopathy, and evaluated the adverse reactions, through the neurological function score (NIHSS , Barthel Index), cognitive score (MoCA, MMSE),and the international uniform Parkinson Rating Scale score (UPDRS). Here, we seek new means for the treatment of hypoxic ischemic encephalopathy, and provide the basis for clinical for further application of umbilical cord blood derived Mesenchymal stem cells.

On the basis of conventional therapy, at the same time, selected patients were given by intravenous infusion of umbilical cord blood stem cells 100-800 million. All patients before treatment, after treatment for 15days, 90days and 180 days were evaluated respectively the curative effect. The neurological function score (NIHSS score, Barthel Index) was observed in patients with the ability to live independently and prognosis; MoCA, MMSE were used in the evaluation of cognitive function ; UPDRS was used in the evaluation of extrapyramidal tract function.

Eligibility

Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

Patients are screened foe enrollment in the study if both clinal signs and laboratory tests meet the diagnosis standards recommended by International Classification of Diseases-10 about hypoxic ischemic encephalopathy.

Exclusion Criteria:

Exclusion Criteria are any clinically significant diseases in liver,kidney,and heart. additional exclusion criteria are no pregnancy,no immunosuppressive medication, no tumor, no viral diseases or diseases associated with immunodeficiency.

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT01962233

Contacts

Contact: Ping Gu, Doctor 86-311-85917297 gpwh2000@126.com

Locations

China, Hebei

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Sponsors and Collaborators

Hebei Medical University

Investigators

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More Information

No publications provided

Responsible Party:	Quanhai Li, Director of Cell Thearpy Center, the First Hospital of HeibeiMU, Hebei Medical University
ClinicalTrials.gov Identifier:	NCT01962233 History of Changes
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Health Authority:	China: Ethics Committee United States: Food and Drug Administration

Additional relevant MeSH terms:

Cerebrovascular **Disorders**
Brain **Diseases**
Central Nervous System **Diseases**
Nervous System **Diseases**
Vascular **Diseases**
Cardiovascular **Diseases**
Delirium, Dementia, Amnestic, Cognitive **Disorders**
Mental **Disorders**
Central Nervous System Viral **Diseases**
Virus **Diseases**
Liver **Diseases**
Digestive System **Diseases**
Brain **Diseases**, Metabolic
Metabolic **Diseases**
Substance-Related **Disorders**

Brain Ischemia
Ischemia
Brain Damage, Chronic
Delirium
Encephalitis
Hepatic Encephalopathy
Neurotoxicity Syndromes
Hypoxia-Ischemia, Brain
Pathologic Processes
Confusion
Neurobehavioral Manifestations
Neurologic Manifestations
Signs and Symptoms
Central Nervous System Infections
Liver Failure

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