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Umbilical Cord Blood Therapy for Cerebral Palsy

This study has been completed.

Sponsor:
MinYoung Kim, M.D.

Information provided by (Responsible Party):
MinYoung Kim, M.D., Bundang CHA Hospital

ClinicalTrials.gov Identifier:
NCT01528436

First received: February 3, 2012
Last updated: July 17, 2012
Last verified: July 2012
History of Changes

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

Purpose

This randomized controlled study aims to evaluate the efficacy of **umbilical cord** blood therapy for children with **cerebral palsy**.

Condition	Intervention	Phase
Cerebral Palsy	Biological: **Umbilical Cord** Blood Infusion Other: Placebo **Umbilical Cord** Blood Other: Active Rehabilitation	Phase 2

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Efficacy Study
Intervention Model: Parallel Assignment
Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor)
Primary Purpose: Treatment

Official Title: **Umbilical Cord** Blood Therapy for **Cerebral Palsy**: a Randomized,Double-blind, Placebo-controlled Trial

Resource links provided by NLM:

MedlinePlus related topics: Cerebral Palsy Paralysis Rehabilitation

U.S. FDA Resources

Further study details as provided by Bundang CHA Hospital:

Primary Outcome Measures:

- Changes in Motor Performance [Time Frame: Baseline - 1 month - 3 months] [Designated as safety issue: No]

  GMPM (Gross Motor Performance Measure) as a standardized measurement tool for assessing quality of movement regarding 3 properties of 5 ones; alignment, coordination, dissociated movement, stability, and weight shift (range: 0~100, Higher value means better motor quality). We will report GMPM scores at each assessment time points.

- Changes in Standardized Gross Motor Function [Time Frame: Baseline - 1 month - 3 months] [Designated as safety issue: No]

  GMFM (Gross Motor Function Measure) as a standardized measurement tool for assessing Gross Motor Function consisting of sub-scales; lying & rolling, sitting, crawling & kneeling, standing, walking, running & jumping (range: 0~100 , Higher value means better gross motor function). We will report GMFM scores at each assessment time points.

Secondary Outcome Measures:

- Changes in Cognitive Neurodevelopmental Outcome [Time Frame: Baseline - 1 month - 3 months] [Designated as safety issue: No]

  Korean version of Bayley Scale of Infant Development-II (K-BSID-II) Mental Scales (higher value means better mental function: 0 - worst, 178 - best). We will report K-BSID-II Mental Scale raw scores at each assessment time points.

- Changes in Motor Neurodevelopmental Outcome [Time Frame: Baseline - 1 month - 3 months] [Designated as safety issue: No]

  Korean version of Bayley Scale of Infant Development-II (K-BSID-II) Motor Scales (higher value means better motor function: 0 - worst, 112 - best). We will report K-BSID-II Motor Scale raw scores at each assessment time points.

- Changes in Functional Independence in Daily Activities [Time Frame: Baseline - 1 month - 3 months] [Designated as safety issue: No]

  WeeFIM (Functional Independence Measure for Children) measures functional independence in daily activities. WeeFIM contains 18 items and each item is ranked from complete dependence (scored as 1) to complete independence (scored as 7). The range is from 18 to 126 and higher scores mean more independent performance in daily activities. We will report total WeeFIM scores measured at each assessment time points.

- Changes in Visual Perception Test [Time Frame: Baseline - 1 month - 3 months] [Designated as safety issue: No]

  We will evaluate visual perception function with one of three measures: DTVP (Developmental Test of Visual Perception), MVPT (Motor-free Visual Perception Test), and VMI (Visual-Motor Integration, Visual Perception and Motor Coordination). All can be scored as percentile rank from 0 to 100. Higher values mean better visual perception ability.

- Changes in Muscle Strength [Time Frame: Baseline - 1 month - 3 months] [Designated as safety issue: No]

  Summation of MMT (manual muscle strength test score): summated scores of the manual muscle strength test (zero=0, trace=1, poor=2, fair=3, good=4, normal=5) for flexors, extensors, abductors, and adductors of bilateral shoulder and hip joints; flexors and extensors of bilateral elbow, wrist, and knee; dorsiflexors and plantar flexors of the ankles (range: 0 ~ 160) Higher scores mean better muscle strength. Categories of outcome table will be summation of MMT scores measured at each assessment time point.

- Changes in Functional Performance in Daily Activities [Time Frame: Baseline - 1 month - 3 months] [Designated as safety issue: No]

  Pediatric Evaluation of Disability Inventory (PEDI) for assessing functional performance in daily activities in children (All values are adjusted and higher value means better functional performance, 0 - worst, 100 - best). We will report 2 scales and 3 domains of each scale: a Functional Skill Scale (FSS) and a Caregiver Assistance Scale (CAS) which are divided respectively into 3 domains: self care, mobility, and social function. Categories of outcome table will be each domain scores measured at each assessment time point.

- Changes in **Brain** Glucose Metabolism Using by **Brain** 18F-FDG PET [Time Frame: Baseline - 2 weeks] [Designated as safety issue: No]

  18F-FDG PET imaging will be underwent twice prior to and then 2 weeks post-treatment. All scans will be reviewed by a nuclear physician. Spatial pre-processing and statistical analyses will be done using SPM8 implanted in Matlab to compare differences in regional brain glucose metabolism between groups and differences between pre- and post-therapy imaging data. We will reported increased areas and decreased areas of glucose metabolism in two groups.

Enrollment:	37
Study Start Date:	February 2012
Study Completion Date:	July 2012
Primary Completion Date:	July 2012 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: **Umbilical Cord** Blood and Rehabilitation Allogeneic **Umbilical Cord** Blood infusion and Active Rehabilitation	Biological: **Umbilical Cord** Blood Infusion The subjects will be undertaken allogeneic **umbilical cord** blood infusion intravenously or intraarterially under non-myeloablative immunosuppression. Other Name: Donated **Umbilical Cord** Blood Units from Affiliated **Cord** Blood Bank Other: Active Rehabilitation All subjects should participate in active rehabilitation. They will receive two physical and occupational therapy sessions per day. Post discharge, each participant should continue to receive rehabilitation therapy at least 3 days per week until the study completion.
Active Comparator: Placebo **Umbilical Cord** Blood and Rehabilitation Placebo **Umbilical Cord** Blood infusion and Active	Other: Placebo **Umbilical Cord** Blood Placebo **Umbilical Cord** Blood that resembles **cord** blood in appearance was designed. Other: Active Rehabilitation All subjects should participate in active rehabilitation. They will receive two physical and occupational therapy sessions per day. Post discharge, each participant should continue to receive rehabilitation therapy at least 3

Rehabilitation	days per week until the study completion.

Detailed Description:
Cerebral palsy is a disorder of movement and posture resulted from a non-progressive lesion or injury of the immature brain. It is a leading cause of childhood onset disability.

Many experimental animal studies have revealed that umbilical cord blood is useful to repair neurological injury in brain.

On the basis of many experimental studies, umbilical cord blood is suggested as a potential therapy for cerebral palsy.

Eligibility

Ages Eligible for Study: 6 Months to 20 Years
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria
Inclusion Criteria:

- Cerebral Palsy with abnormal muscle tone
- Gross Motor Function Classification System (GMFCS): I, II, III, IV, V
- Willing to comply with all study procedure

Exclusion Criteria:

- Medical instability including pneumonia or renal function at enrollment
- Presence of known genetic disease
- Presence of drug hypersensitivity which is related to this study remedy
- Poor cooperation of guardian,including inactive attitude for rehabilitation and visits for follow-up
- Decision by the principal investigator when there are unexpected events including brain surgery, that may affect the outcome

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT01528436

Locations

Korea, Republic of

CHA Bundang Medical Center, CHA University
Seongnam-si, Gyeonggi-do, Korea, Republic of, 463-712

Sponsors and Collaborators

MinYoung Kim, M.D.

Investigators

Principal Investigator: Minyoung Kim, M.D., Ph.D. CHA Bundang Medical center, CHA university

More Information

No publications provided

Responsible Party: MinYoung Kim, M.D., Associate Professor, Bundang CHA Hospital
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Study First Received: February 3, 2012
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Keywords provided by Bundang CHA Hospital:
Cerebral Palsy
Umbilical Cord Blood
Rehabilitation

Additional relevant MeSH terms:

Cerebral Palsy	Central Nervous System Diseases
Paralysis	Nervous System Diseases
Brain Damage, Chronic	Neurologic Manifestations
Brain Diseases	Signs and Symptoms

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