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Trial record **1 of 9** for: Alzheimer's Disease and cord blood

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The Safety and The Efficacy Evaluation of NEUROSTEM®-AD in Patients With Alzheimer's Disease

This study has been completed.

Sponsor:
Medipost Co Ltd.

Information provided by (Responsible Party):
Medipost Co Ltd.

ClinicalTrials.gov Identifier:
NCT01297218

First received: February 11, 2011
Last updated: April 19, 2012
Last verified: April 2012
History of Changes

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

Purpose

The primary purpose of this study is to evaluate the safety and the tolerability of NEUROSTEM®-AD (Human Umbilical **Cord Blood** Derived Mesenchymal Stem Cells) and to assess the maximum tolerated dose (MTD). This study is also to investigate the efficacy of this study drug in patients with **dementia of Alzheimer's type**.

Condition	Intervention	Phase
Dementia of the Alzheimer's Type	Biological: Human Umbilical **Cord Blood** Derived-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: Open-Label, Single-Center, Phase 1 Clinical Trial to Evaluate the Safety and the Efficacy of NEUROTSTEM®-AD in Patients With **Dementia of the Alzheimer's Type**

Resource links provided by NLM:

Genetics Home Reference related topics: Alzheimer disease

MedlinePlus related topics: Alzheimer's Disease Dementia

U.S. FDA Resources

Further study details as provided by Medipost Co Ltd.:

Primary Outcome Measures:

- Number of participants with Adverse event [Time Frame: 12 weeks from post-administration] [Designated as safety issue: Yes]

  Number of participants with adverse event, number of participants with normal range of vital signs, mixed lymphocyte reaction, and laboratory examination

Secondary Outcome Measures:

- Changes from the baseline in ADAS-cog at 12 weeks post-dose [Time Frame: 12 weeks from post-administration]
  [Designated as safety issue: No]

  Changes from the baseline in ADAS-cog, S-IADL, K-MMSE, CGA-NPI, ADAS-Cog, serum transthyretin, amyloid beta and tau in cerebrospinal

fluid, PIB-PET and FDG-PET at 12 weeks post-dose.

Enrollment:	9
Study Start Date:	February 2011
Study Completion Date:	December 2011
Primary Completion Date:	September 2011 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: NEUROSTEM®-AD	Biological: Human Umbilical **Cord Blood** Derived-Mesenchymal Stem Cells DOSE A - 250,000 cells per 5 uL per 1 entry site, 3 million cells per brain DOSE B - 500,000 cells per 5 uL per 1 entry site, 6 million cells per brain Other Name: NEUROSTEM®-AD

Detailed Description:

Most of the treatments for Alzheimer disease are chemical drug that is designed to temporarily increase acetylcholine, based on the cholinergic hypothesis. These drugs can improve the symptoms but is not able to inhibit the disease progression. New drugs from the disease have been developed but they have not been successful yet.

Mesenchymal stem cells (MSC) are capable of differentiating into various tissues. Due to the characteristics of the cells it has been widely investigated in tissue regeneration. In addition, the paracrine effect of MSC in microenvironment has been recently reported. MSC has been developed as an immunomodulation cell therapy product because it has been known that it does not cause immunological rejection in allo- and xeno-transplantation. Clinical studies showed that umbilical cord blood-derived MSC is immunologically stable and not toxic.

This study is to evaluate the safety and the tolerability of NEUROSTEM®-AD (Human Umbilical Cord Blood Derived Mesenchymal Stem Cells) and to assess the maximum tolerated dose (MTD). This study is also to investigate the efficacy of this study drug in patients with dementia of Alzheimer's type.

Eligibility

Ages Eligible for Study:	50 Years to 75 Years
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Korean men and women who are age 50 or older
- Dementia as determined by DSM-IV criteria
- Probable alzheimer's disease as determined by NINCDS-ADRDA criteria
- K-MMSE score in the range of 10 to 24
- Positive result of PIB-PET imaging (SUV > 1.5,when comparing the result for the cerebellum with the result for the frontal lobe)
- Voluntarily participating subject who sign the consent form

Exclusion Criteria:

- Subject with psychological diseases (i.e. depression, schizophrenia, bipolar disorder, etc)
- Subject with dementia caused by other than Alzheimer's disease (i.e. infection of central nervous system, Creutzfeld-Jacob disease, severe head trauma, Pick's disease, Huntington's disease, and Parkinson's disease)
- Subject with vascular dementia as determined by the clinical criteria of DSM IV and the imaging criteria of Erkinjuntii
- Subject with severe white matter hyperintensities (WMH); Severe WMH is defined that length of the deep white matter is 25 mm or longer and length of the periventricular capping/banding is 10 mm or longer.
- Subject who have had stroke in 3 months.
- Subject with liver disease (two times higher than normal range of ALT/AST)
- Subject with severe kidney failure (1.5mg/dL of serum creatinine or more)
- Pregnant women or lactating women
- Hemoglobin < 9.5g/dL for men, < 9.0 g/dL for women; Total WBC count < 3000/mm3; Total bilirubin ≥ 3 mg/dL
- Subject who is suspect to have active lung diseases, based on check X-ray result from Visit 1
- Women of childbearing age who reject to practice contraception
- Subject who have been excluded in the subject selection process for this study before
- A platelet count < 150,000/mm3; PT ≥ 1.5; INR or aPTT ≥ 1.5 X control

- Subject with cancer
- History of alcohol or drug abuse
- Subject who cannot undergo MRI, CT, or PET screening
- Subject who cannot undergo anesthesia or stereotactic brain injection
- Subject who is determined inappropriate by the investigators

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT01297218

Locations

Korea, Republic of

Samsung Medical Center
Seoul, Korea, Republic of

Sponsors and Collaborators

Medipost Co Ltd.

Investigators

Principal Investigator: Duk L. Na, M.D. Samsung Medical Center

More Information

No publications provided

Responsible Party:	Medipost Co Ltd.
ClinicalTrials.gov Identifier:	NCT01297218 History of Changes
Other Study ID Numbers:	MP-CR-007
Study First Received:	February 11, 2011
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Health Authority:	Korea: Food and Drug Administration

Keywords provided by Medipost Co Ltd.:
Alzheimer, Mesenchymal Stem Cells, Umbilical **Cord Blood**

Additional relevant MeSH terms:
Alzheimer Disease
Dementia
Brain **Diseases**
Central Nervous System **Diseases**
Nervous System **Diseases**
Tauopathies
Neurodegenerative **Diseases**
Delirium, Dementia, Amnestic, Cognitive **Disorders**
Mental **Disorders**

ClinicalTrials.gov processed this record on September 22, 2013