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The Long-Term Safety and Efficacy Follow-Up Study of Subjects Who Completed the Phase I Clinical Trial of Neurostem®-AD

This study is currently recruiting participants.

Verified September 2012 by Samsung Medical Center

Sponsor:
Duk Lyul Na

Collaborator:
Medipost Co Ltd.

Information provided by (Responsible Party):
Duk Lyul Na, Samsung Medical Center

ClinicalTrials.gov Identifier:
NCT01696591

First received: September 7, 2012
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History of Changes

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

Purpose

The purpose of the study is to determine the long-term safety and exploratory efficacy of NEUROSTEM®-AD, administered via an open brain surgery to subjects with **dementia of the Alzheimer's type**, who were eligible for and enrolled in the earlier part of the phase I. Aside from the subjects who completed the earlier part of the Phase I, 3 additional subjects with comparable demographics and **disease** characteristics as the treatment group will be enrolled into a control group, followed-up for 3 months, and compared for various **disease** progression indicators with the treatment group.

The hypothesis is that NEUROSTEM®-AD is safe and effective in the treatment of **dementia of the Alzheimer's type**.

Condition	Intervention
Alzheimer Disease Dementia Brain **Diseases** Central Nervous System **Diseases** Nervous System **Diseases** Tauopathies Neurodegenerative **Diseases** Delirium, Dementia, Amnestic, Cognitive **Disorders** Mental **Disorders**	Biological: NEUROSTEM®-AD

Study Type: Observational
Study Design: Observational Model: Case Control
Time Perspective: Prospective

Official Title: The Long-Term Safety and Efficacy Follow-up Study of Subjects Who Completed the Phase I Clinical Trial of Neurostem®-AD

Resource links provided by NLM:

Genetics Home Reference related topics: Alzheimer disease

MedlinePlus related topics: Alzheimer's Disease Brain Diseases Degenerative Nerve Diseases Delirium Dementia Mental Disorders Neurologic Diseases Psychotic Disorders

U.S. FDA Resources

Further study details as provided by Samsung Medical Center:

Primary Outcome Measures:

- Safety [Time Frame: upto 24 months post-op] [Designated as safety issue: Yes]

  Incidence rate ot adverse events (vital signs, physical examination, mixed lymphocyte reaction, and laboratory tests)

Secondary Outcome Measures:

- Efficacy [Time Frame: upto 24 months post-op] [Designated as safety issue: No]

  Primary Efficacy Variable: ADAS-cog response rate, ADAS-cog response is defined as when ADAS-cog score at the end of the study is not worse than the Baseline score. Secondary Efficacy Variables:

  - Changes in Seoul Instrumental Activities of Daily Living (S-IADL)
  - Changes in Mini Mental State Examination Korean verson (K-MMSE)
  - Changes in Caregiver-administered Neuropsuchiatric Inventory
  - Changes in Alzheimer's Disease Assessment Scale-Cognitive Subscale (ADAS-Cog)
  - Changes in CMRglc: regional cerebral metabolic rate for glucose (FDG-PET)

Estimated Enrollment:	14
Study Start Date:	March 2012
Estimated Study Completion Date:	September 2013
Estimated Primary Completion Date:	September 2013 (Final data collection date for primary outcome measure)

Groups/Cohorts	Assigned Interventions
NEUROSTEM®-AD A single administration of human umbilical **cord blood**-derived mesenchymal stem cells through a brain surgery DOSE A - 250,000 cells per entry site, 3 million cells per brain; DOSE B - 500,000 cells per entry site, 6 million cells per brain	Biological: NEUROSTEM®-AD NEUROSTEM®-AD was administered to eligible subjects in the early part of the Phase I clinical study. In this follow-up study, no intervention will be performed. Other Name: human umbilical **cord blood**-derived mesenchymal stem cells (hUCB-MSCs)
Control Group A group of subjects with comparable demographics (age and gender) and **disease** characteristics [Clinical Dementia Rating Scale Sum of Boxes (CDR-SOB)] as the NEUROSTEM®-AD-treated group, but did not receive the treatment with NEUROSTEM®-AD and were continued on conventional therapy. Restrictions in the concurrent use of drug therapy are as follows: Patients are, in principle, permitted to continue the drug therapy they were on prior to the enrollment, for the treatment of concurrent illnesses other than Dementia, such as hypertension, diabetes mellitus, or hyperlipidemia. For drugs used in the treatment of dementia, behavior-modifying drugs can be added to the pharmacological regimen of a subject during the course of the study. However, adding a new cognitive enhancer, such as donepezil, memantine, galantamine, rivastigmine, is not permitted while dose adjustment is permitted given that the drug had been in use prior to the initiation of the study.	

Detailed Description:
This is a long-term follow up study of the earlier part of the phase I, during which the safe and effective dose(safety) of NEUROSTEM®-AD was determined for implantation into the brains of subjects with Dementia of the Alzheimer's type. Subjects with Dementia of the Alzheimer's type, who signed the informed consent form and meet the eligibility criteria, were implanted with a single dose of NEUROSTEM®-AD, hUBC-MSCs, into the brain. The subjects were hospitalized for 5 to 10 days following the surgical implantation and were observed for acute adverse events: Gradient echo MRI within the the 24 hours post-op, vital signs, clinical laboratory tests, chest x-rays within Day 2. On Day 14, DLT was assessed, and the subjects were followed up on the safety and disease progression of dementia (of the Alzheimer's type) for 12 weeks post-implantation.

In this part of the study, the subjects described above will be followed-up for upto Month 24, and 3 additional subjects with comparable demographics and disease characteristics as the treatment group (refer to Inclusion/Exclusion Criteria) will be enrolled as a control group, followed up for 3 months and compared with the treatment group for various indicators of the disease progression.

Eligibility

Ages Eligible for Study:	50 Years to 75 Years
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No
Sampling Method:	Non-Probability Sample

Study Population

The patients, who were administered with NEUROSTEM®-AD in the earlier part of the Phase I study, will be compared with the patients, who have similar demographics and disease characteristics as the subjects in the test group but have not been treated with NEUROSTEM®-AD.

Criteria

TEST GROUP

Inclusion Criteria:

- Subjects who have enrolled and completed the Phase I cliical trial: The Safety and The Efficacy Evaluation of NEUROSTEM®-AD in Patients With Alzheimer's Disease
- Subjects who are willing to participate in the study and sign the consent form

Exclusion Criteria:

- Females who are pregnant or nursing
- Subjects who have participated in another clinical study within the 3 months prior to the initiation of this study
- Subjects who are restricted from undergoing exams perfomed during the study (i.e. MRI, CT, or PET screening)
- Subjects who the principal investigator considers inappropriate for participation in the study due to any reasons other than those listed above

CONTROL GROUP

Inclusion Criteria:

- Patients with a moderate alzheimer's disease, diagnosed with a dementia of alzheimer's type, according to the DSM-VI and NINCDS-ADRDA criteria, and shows amyloid-positive in a PIB-PET

Exclusion Criteria:

- Subjects with a psychological disease (i.e. depression, schizophrenia, bipolar disorder, etc)
- Subjects with a dementia caused by other degenerative neurological diseases (infection of the CNS, such as HIV or Syphilis), head trauma, Creutzfeld-Jacob disease, Pick's disease, Huntington's disease, and Parkinson's disease)
- Subjects with a vascular dementia as determined by the clinical criteria of DSM IV and the imaging criteria of Erkinjuntii
- Subjects with severe white matter hyperintensities (WMH); Severe WMH is defined as, according to Clinical Research Center for Dementia of South Korea, a condition in which the deep white matter is 25 mm or greater and the periventricular capping/banding is 10 mm or greater in lengths.
- Subjects with a history of stroke within the 3 months prior to the study enrollment
- Subjects with a severe liver disease (ALT/AST values are higher than twice the normal range)
- Subjects with a severe renal disease (1.5mg/dL or more of serum creatinine)
- Pregnant or lactating women
- Subjects with abnormal findings of the clinical laboratory values at Visit 1:
- Hemoglobin < 9.5g/dL in male < 9.0 g/dL in female
- Total WBC count < 3000/mm3
- Total bilirubin ≥ 3 mg/dL
- Subjects with a suspected active lung disease, based on the chest X-ray result at Visit 1
- Females of childbearing age who does not practice medically acceptable method of contraception during the study
- Subjects who have previously failed Screening for participation in this study
- Subjects who have participated in another clinical study within the 3 months prior to the initiation of this study
- Subjects with a bleeding disorder (platelet count < 150,000/mm3; PT ≥ 1.5; INR or aPTT ≥ 1.5 X control
- Subjects with a cancer (including brain tumor)
- Subjects with a history of alcohol or drug abuse
- Subjects who are restricted from undergoing exams perfomed during the study (i.e. MRI, CT, or PET screening)
- Patients who the principal investigator considers inappropriate for participation in the study due to any reasons other than those listed above

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT01696591

Contacts

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Locations

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Sponsors and Collaborators

Duk Lyul Na

Medipost Co Ltd.

Investigators

Principal Investigator: Duk L. Na, MD,PhD Samsung Medical Center

More Information

Additional Information:

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

No publications provided

Responsible Party:	Duk Lyul Na, Professor of Neurology, Sungkyunkwan University School of Medicine, Samsung Medical Center
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Keywords provided by Samsung Medical Center:
Alzheimer, Mesenchymal Stem Cells, Umbilical **Cord Blood**

Additional relevant MeSH terms:
Alzheimer Disease
Mental **Disorders**
Psychotic **Disorders**
Brain **Diseases**
Central Nervous System **Diseases**
Cognition **Disorders**
Nervous System **Diseases**
Delirium, Dementia, Amnestic, Cognitive **Disorders**
Neurodegenerative **Diseases**
Schizophrenia and **Disorders** with Psychotic Features
Delirium
Dementia
Tauopathies
Confusion
Neurobehavioral Manifestations
Neurologic Manifestations
Signs and Symptoms

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