Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Safety and Therapeutic Effect of Autologous Bone Marrow Mesenchymal Stem Cell Transplantation in Children with Cerebral Palsy: Clinical Trial Phase I-II

Protocol summary

Study aim
Evaluation safety and efficacy of bone marrow mesenchymal stem cells in children with cerebral palsy

Design
this study is a clinical trial with a control group, with parallel groups, non-randomized, phase I-II, on 46 patients.

Settings and conduct
46 patients with confirmed cerebral palsy in this study will be divided into control and cell therapy groups (23 patients in each groups). Patients will be screened 1, 3, 6,12 months after cell injection. The study site will be Shohada Tajrish Hospital.

Participants/Inclusion and exclusion criteria
Inclusion criteria: definitive diagnosis of cerebral palsy; no seizures or with controlled seizures; parental consent. Exclusion criteria: severe cognitive disease; hydrocephalus; coagulation diseases; diseases such as cancer, active infections and heart, kidney and liver diseases; evidence of a progressive neurological disease; evidence of a genetic disease.

Intervention groups
Intervention group: In this group, stem cells will be isolated by bone marrow aspiration. After culturing and preparing the cells, MSC cells will be transplanted at a concentration of 1 million cells per ml prepared through a puncture lumbar in the L4 / L5 region. Patients will undergo periodic examinations in neurology clinic at regular intervals after transplantation. patients' sensory and motor function, spasticity and balance will be assessed. Control group: In this group, patients do not receive cell injection and receive supportive therapies.

Main outcome variables
Motor System Functioning; Balance Assessment; Spasticity Assessment; Motor and Cognitive Disability Assessment; Side Effects of cell injection.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200502047277N5**
Registration date: **2021-01-15, 1399/10/26**
Registration timing: **registered_while_recruiting**

Last update: **2021-01-15, 1399/10/26**
Update count: **0**

Registration date
2021-01-15, 1399/10/26

Registrant information

Name
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Name of organization / entity

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Iran (Islamic Republic of)

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+98 21 25719

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-10-22, 1397/07/30

Expected recruitment end date
2021-10-22, 1400/07/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Safety and Therapeutic Effect of Autologous Bone Marrow Mesenchymal Stem Cell Transplantation in Children with Cerebral Palsy: Clinical Trial Phase I-II

Public title
Investigation of the Effect of Stem Cells Injection in Children with Cerebral Palsy

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Definitive diagnosis of cerebral palsy No seizures or with controlled seizures Parental consent

Exclusion criteria:
Severe cognitive disease Hydrocephalus Coagulation diseases Have diseases such as cancer, active infections and heart, kidney and liver diseases Evidence of a progressive neurological disease Evidence of a genetic disease

Age
From **1 year** old to **18 years** old

Gender
Both

Phase
1-2

Groups that have been masked
No information

Sample size
Target sample size: **46**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shahid Beheshti University of Medical Sciences

Street address
Shahid Beheshti University of Medical Sciences, Shahid Arabi St., Yemen St., Shahid Chamran Highway, Tehran

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Tehran

Province
Tehran

Postal code
1985717443

Approval date
2020-12-28, 1399/10/08

Ethics committee reference number
IR.SBMU.REC.1399.037

Health conditions studied

1

Description of health condition studied
Cerebral palsy

ICD-10 code
G80

ICD-10 code description
Cerebral palsy

Primary outcomes

1

Description
Motor System Functioning

Timepoint
Before injection, 3, 6 and 12 months after the intervention

Method of measurement
Physical examination and motor function will be evaluated by the Gross Motor Function Measure (GMFM-66) and Gross Motor Function Classification System (GMFCS)

2

Description
Balance Assessment

Timepoint
Before injection, 3, 6 and 12 months after the intervention

Method of measurement
Physical examination and Berg Balance Scale will be used to evaluate the balance

3

Description
Spasticity Assessment

Timepoint
Before injection, 3, 6 and 12 months after the intervention

Method of measurement
Physical examination and Grading of spasticity will be classified by the Modified Ashworth Scale which consist of 5 grades where 0 represents no increase in muscle tone and 5 is rigidity in flexion and extension in the affected part.

4

Description
Motor and Cognitive Disability Assessment

Timepoint
Before injection, 3, 6 and 12 months after the intervention
Method of measurement
Physical examination and Functional Independence Measure (FIM) and Functional Assessment Measure (FAM) will be used to measure patient motor and cognitive disability in a wide range of conditions.

5

Description
Evaluation the side effects of autologous bone marrow derived mesenchymal stem cells transplantation in cerebral palsy patients
Timepoint
1, 3, 6 and 12 months after injection
Method of measurement
Adverse effects will be assessed based on common terminology criteria for adverse events (CTCAE, version 4.3)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: At first, the patient's personal and demographic information will be recorded completely. The necessary questionnaires and physical examinations will be performed and the results will be recorded. In this group, patients' stem cells will be isolated by bone marrow aspiration. After culturing and preparing the cells, MSC cells will be transplanted at a concentration of 1 million cells per ml prepared through a puncture lumbar in the L4 / L5 region. Patients will undergo periodic examinations in neurology clinic at regular intervals after transplantation. patients' sensory and motor function, spasticity and balance will be assessed. In addition, patients are examined for complications such as headache, stiff neck, nausea and vomiting, shortness of breath, jaundice and infection,....
Category
Treatment - Other

2

Description
Control group: In this group, patients do not receive cell injection and receive supportive therapies.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shohadaye Tajrish Hospital
Full name of responsible person
Saeed Oraee Yazdani
Street address
Shohadaye Tajrish Hospital, Tajrish Square, Tehran.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Afshin Zarghi
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7th Floor, Building Number.2, Shahid Beheshti University of Medical Sciences, Arabi Avenue, Daneshjoo Blvd, Velenjak, Tehran, Iran.
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Saeed Oraee Yazdani
Position
Assisstant professor
Latest degree
Specialist
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Neurosurgery
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available