

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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

saeed oraei yazdani

Name of organization / entity

Country

Iran (Islamic Republic of)

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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

City

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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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Full name of responsible person

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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

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Neurosurgery

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Latest degree

Specialist

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Research Associate

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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