Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

A Triple blinded, Parallel Randomized clinical trial Phase II&III of 3 Times Intrathecal Injections of an Umbilical Cord-Derived Mesenchymal Stromal Cell Product “WhartoCell” in Children with Cerebral Palsy

Protocol summary

Study aim

This study designed for the evaluation of safety and therapeutic effects of intrathecal injection (ITI) of mesenchymal stem cells (MSC) derived from allogenic umbilical cord (Whartocell) in change of developmental functions of spastic cerebral Palsy (CP) in comparison with control group .

Design

Three arm parallel group, triple blind, blocked randomized controlled trial phase 2-3 .

Settings and conduct

150 cases of Spastic CP cases between 2-14 years that have inclusion criteria will be selected and randomly divided in 2 groups of injection of MSC derived from umbilical cord and control of no injection .The trial is triple blind and the participants, clinical evaluators and investigators are unaware of study groups .

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Participants/Inclusion and exclusion criteria

Diparetic, quadriparetic and hemiparetic spastic CP Between the ages of 2-14 years Gross motor function classification (GMFC) between 2 -4 Brain MRI finding compatible with CP Exclusion criteria : Other types of CP Normal brain MRI Uncontrolled seizures Serious diseases of other organs

Intervention groups

Intervention group: Three ITI of MSC every 2 weeks Control group: without injection, that after needle insertion into the skin without entrance to CSF space needle withdrawn and only simulation of ITI was done without the awareness of the participants . All of the participants had a baseline brain neuroimaging, that will be repeated after 12 months . Patients will be evaluated by predicted scales during the 12 months and will be followed for similar rehabilitation protocol.

Main outcome variables

Motor development alteration by GMFM 66, Change of GMFCS, Change of motor function by Manual Ability Classification System (MACS), Change of motor function by Pediatric Disability Inventory (PEDI) Score, Spasticity change by Ashworth Scale, Change of quality of life (QOL) by CP QOL Questionnaire.

General information

Reason for update

Acronym

MSCCP

IRCT registration information

IRCT registration number: **IRCT20110628006907N18**
Registration date: **2023-03-11, 1401/12/20**
Registration timing: **prospective**

Last update: **2023-03-11, 1401/12/20**
Update count: **0**

Registration date

2023-03-11, 1401/12/20

Registrant information

Name

Mahmoudreza Ashrafi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 6612 9252

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-05, 1402/02/15

Expected recruitment end date

2024-05-04, 1403/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Triple blinded, Parallel Randomized clinical trial Phase II&III of 3 Times Intrathecal Injections of an Umbilical Cord-Derived Mesenchymal Stromal Cell Product “WhartoCell” in Children with Cerebral Palsy

Public title

Effects of umbilical cord derived mesenchymal stem cells injection in the treatment of children with cerebral palsy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Spastic cerebral palsy (Dip, Quadri, Hemiparetic) Ages between 2 - 14 years Gross motor function classification (GMFC) 2 -4 No seizure disorder or with controlled seizure Acquired brain MRI finding compatible with CP Informed consent of parents

Exclusion criteria:

Normal brain MRI Progressive neurological diseases Congenital brain cortical malformations TORCH infections(Toxoplasmosis, Others, Rubella Cytomegalovirus Hepatitis C) Other types of cerebral palsy (athetoid , atonic , ataxic , mixed) Acute infections (Human Immunodeficiency Virus , Hepatitis C Virus) Hemorrhagic diathesis Severe anemia (Hemoglobin less than 8) Ventilator dependent pulmonary diseases Severe renal dysfunction Severe liver dysfunction

Age

From **2 years** old to **14 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients are randomly allocated into two groups of intervention and control using a balanced block randomization technique. To do that, they were divided into blocks of 6 and 9. All subjects randomly allocated with online randomization software to generate random-number sequences. {Sealed Envelope Ltd. 2015. Create a blocked randomization list. [Online] Available from: https://www.sealedenvelope.com/simple-randomiser/v1/lists [Accessed 15 Dec 2015]}. Coordinator and Physician responsible for assessing inclusion / exclusion criteria and registering individuals are blind.

Blinding (investigator's opinion)

Triple blinded

Blinding description

As this study designed as triple blind, In the control group after insertion of the needle into the skin with an appearance of simulating of lumbar puncture no injection were done without the awareness of the patients or their parents and clinical evaluators . At the end of the study if safety and effectiveness of cell therapy will be proved , for ethical consideration cell therapy will be performed for control group

Placebo

Not used

Assignment

Parallel

Other design features

Designing of 3 injection of stem cells with defined interval in intervention group - including of hemiparetic CP in the study

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Research Institute for Oncology Hematology and Cell therapy- Tehran Un

Street address

North Kargar, Jalale aleahmad Cross Dr Shariati Hospital

City

Tehran

Province

Tehran

Postal code

1411713135

Approval date

2023-01-09, 1401/10/19

Ethics committee reference number

IR.TUMS.HORCSCT.REC.1401.023

Health conditions studied

1

Description of health condition studied

Spastic Cerebral Palsy

ICD-10 code

G80.0

ICD-10 code description

Spastic quadriplegic cerebral palsy

Primary outcomes

1

Description
Motor development alteration with GMFM 66 score
Timepoint
Before intervention , 3 months after first intervention ,6 months after first intervention , 12 months after first intervention
Method of measurement
GMFM 66 score Questionnaire

2

Description
Change of motor function with GMFCS score
Timepoint
Before intervention, 3 months after first intervention, 6 months after first intervention, 12 months after first intervention
Method of measurement
GMFCS Questionnaire

3

Description
Change of motor function according to PEDI score
Timepoint
Before intervention, 3 months after first intervention, 6 months after first intervention, 12 months after first intervention
Method of measurement
PEDI Questionnaire

4

Description
Change of motor function according to MACS score
Timepoint
Before intervention, 3 months after first intervention, 6 months after first intervention, 12 months after first intervention
Method of measurement
MACS Questionnaire

5

Description
Spasticity change of patients according to Ashworth scale
Timepoint
Before intervention, 3 months after first intervention, 6 months after first intervention, 12 months after first intervention
Method of measurement
Ashworth Questionnaire

6

Description
Change of quality of life
Timepoint
Before intervention, 6 months after first intervention, 12 months after first intervention
Method of measurement
CPQOL Questionnaire

Secondary outcomes

1

Description
Probable Change of brain lesions
Timepoint
Before intervention, 1 year after first intervention
Method of measurement
Brain Magnetic Resonance Imaging (MRI), Brain Magnetic Resonance Spectroscopy (MRS), Brain Deep Tensor Imaging (DTI)

2

Description
Number of participants experiencing adverse effects and serious adverse effects
Timepoint
First 24 hours after injection and then any time if occurred
Method of measurement
Questionnaire, parents report and periodic planned clinical evaluations

Intervention groups

1

Description
Intervention group: CP patients receiving ،three intrathecal injection of 20 millions allogenic mesenchymal stem cells derived from umbilical cord (whartocell) , prepared by Cell Thec Pharmed Company. Interval of injections is every 2 weeks . Intrathecal injection will be done under anesthesia via lumbar puncture . After taking 3-5 milliliter of cerebrospinal fluid , 2 milliliter prepared stem cells will be injected with a syringe . The patient will be admitted for one day for monitoring of probable adverse reactions . One year follow up and evaluation with regular similar rehabilitative therapy will be done .
Category
Treatment - Other

2

Description
Control group: : CP patients without injection, that after insertion of needle into the skin without entering into the cerebrospinal fluid space, needle will be withdrawn without any injection and only with an appearance of simulation of lumbar puncture without the awareness of the patient or their parents. The patient will be admitted one day for monitoring of probable adverse reaction . One year follow up and evaluation with regular similar rehabilitative therapy will be done
Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Children's Medical Center

Full name of responsible person
Reza Shervin Badv

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Children's Medical Center Hospital, No 62, Gharib Street, end of keshavarz Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
ROYAN stem cell technology Co

Full name of responsible person
Morteza zarrabi

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Web page address

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
ROYAN stem cell technology Co

Proportion provided by this source
50

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Persons

2

Sponsor

Name of organization / entity
Celltechphamed Co.

Full name of responsible person
Mahdi Hadi

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Hadi@celltech.co

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Celltechphamed Co.

Proportion provided by this source
50

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Anahita Majmaa

Position
Treatment Member

Latest degree
Subspecialist

Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

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Morteza Heidari
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is 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
Title and more details about the data/document
All collected deidentified IPD can be shared6 months after publication
When the data will become available and for how long
6 months after publication
To whom data/document is available
People working in academic institutions and people working in businesses
Under which criteria data/document could be used
Planning of similar studies in other academic centers
From where data/document is obtainable
Email address
What processes are involved for a request to access data/document
After request during the 1-2 months
Comments