Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of safety and motivation status of patients with cerebellar ataxia after intrathecal treatment with mesenchymal stem cells

Protocol summary

Study aim
Evaluating the safety and efficacy of mesenchymal stem cell therapy in patients with cerebellar ataxia

Design
Clinical trial with a control group, with parallel groups, unblinded, randomized, phase 1 on 20 patients. The random number table of the software was used for randomization.

Settings and conduct
Ten patients with cerebellar ataxia receive 50-70 million autologous bone marrow-derived MSCs at Pasteur Hospital. In the control group, other common treatments are prescribed for patients.

Participants/Inclusion and exclusion criteria
inclusion criteria : people aged 10-65 years and with a definitive diagnosis of ataxia and no history of other mental illnesses. Exclusion criteria : pregnancy or a history of other serious mental and non-mental illnesses.

Intervention groups
Intervention group: 10 patients with cerebellar ataxia receiving mesenchymal stem cells Control group: 10 patients with cerebellar ataxia who will receive routine treatments.

Main outcome variables
*-neurologic sign of patients including: Scale for the Assessment and Rating of Ataxia (SARA)-Quality of life-Depression-Beck Scale-Improve in international Co-Operative Ataxia Rating Scale-Balance Test-Tremor Rating Scale *-Before the intervention, month 3 and month 6 after the intervention *-Clinical examination and questionnaire

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160809029275N3**
Registration date: **2022-08-31, 1401/06/09**
Registration timing: **retrospective**

Last update: **2022-08-31, 1401/06/09**
Update count: **0**

Registration date
2022-08-31, 1401/06/09

Registrant information
Name
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 51376276015
Email address
tavakolaj@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-07-23, 1400/05/01

Expected recruitment end date
2022-07-23, 1401/05/01

Actual recruitment start date
2021-09-04, 1400/06/13

Actual recruitment end date
2022-06-30, 1401/04/09

Trial completion date
2022-06-30, 1401/04/09

Scientific title
Evaluation of safety and motivation status of patients with cerebellar ataxia after intrathecal treatment with mesenchymal stem cells

Public title
cerebellar ataxia treatment with mesenchymal stem cells

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Does not receive stem cells in the last 6 months. signing the written consent form by the participants. The age range of 10-65 years without limitation in sex. Definitive diagnosis of ataxia based on brain and cervical spinal cord MRI. Presence of cerebellar or brainstem atrophy and/or cervical spinal cord. Not having other mental illness such as schizophrenia etc.

Exclusion criteria:

Positive pregnancy test. Heart, kidney and liver failure, epilepsy, lung disease, cardiac arrhythmia, diabetes, leukemia and other diseases of the central nervous system such as Parkinson's. If the total level of bilirubin is greater than 1.5 times the upper limit of its normal value. History of chronic or acute alcohol consumption The presence of evidence of seizures in the brain scan Any evidence of infection History of severe drug sensitivity or anaphylaxis to two or more foods or drugs Other organic brain diseases HIV positive and tumor markers positive Patients with severe psychosis, cognitive disorders and inability to understand or sign consent Other organic or systemic diseases Uncontrollable high blood pressure Participation in other clinical trials in the last three months The presence of thyroid disease Presence of evidence of encephalitis Presence of sarcoidosis and Behcet's disease Vitamin E deficiency Wilson's disease Increased blood ammonia Positive anti-GAD and anti-neuronal antibodies Lupus and Wegener's disease Middle ear dysfunction

Age

From **10 years** old to **65 years** old

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **20**

Actual sample size reached: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

A simple randomization method using the random number table method was used to assign patients to groups. In this method, even numbers were placed in the intervention group and odd numbers were randomly placed in the control group.

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 Mashhad University of Medical Sciences

Street address

Mashhad,Daneshgah Street, Qurashi Building, Mashhad University of Medical Sciences

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Approval date

2022-07-02, 1401/04/11

Ethics committee reference number

IR.MUMS.REC.1401.128

Health conditions studied

1

Description of health condition studied

Diagnosis Code G32.81: Cerebellar ataxia

ICD-10 code

G32.81

ICD-10 code description

Cerebellar ataxia in diseases classified elsewhere

Primary outcomes

1

Description

neurologic sign of patients including: Scale for the Assessment and Rating of Ataxia (SARA)-Quality of life-Depression-Beck Scale-Improve in international Co-Operative Ataxia Rating Scale-Balance Test-Tremor Rating Scale

Timepoint

Before the intervention, month 3 and month 6 after the intervention

Method of measurement

Clinical examination and questionnaire

2

Description

Blood markers including: • T4 and TSH• Alpha-fetoprotein• IgG and IgE• OGTT and FBS• ACE• Vitamin E• Electrophoresis of serum proteins• Chol, TG, LDL and HDL• Ceruloplasmin, Cu and 24-hour urine Cu for patients less than 40 years old• Anti-GAD, Anti-dsDNA, P-ANCA and C-ANCA• Vitamin B12 and folic acid

Timepoint

Before the intervention, month 3 and month 6 after the intervention

Method of measurement

Laboratory methods such as electrophoresis, VIDAS and ELISA

3

Description
Investigating the safety of stem cell treatment in patients participating in the study
Timepoint
24-48 hours after receiving injections and the third and sixth months
Method of measurement
Clinical examination of patients to check for fever, headache or any possible allergic reactions.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients receiving 50-70 million autologous MSCs derived from bone marrow
Category
Treatment - Drugs

2

Description
Control group: Control group: patients with cerebellar ataxia who will receive routine treatments including vitamin E, CoQ10, physical therapy and occupational therapy.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Pasteur hospital
Full name of responsible person
Dr. Amir Reza Boroumand
Street address
Ahmad Abad St. Pasteur Av. Pasteur Hospital
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09194216791
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info@pastorno-hospital.com
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr Majid Ghayour Mobarhan
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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
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Dr. Amir Reza Boroumand
Position
specialist
Latest degree
Subspecialist
Other areas of specialty/work
Neuroscience
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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Seyyed Jalil tavakol afshari

Position

prof.

Latest degree

Ph.D.

Other areas of specialty/work

Immunology

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Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr.Seyad Jalil Tavakol Afshari

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Immunology

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Email

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

there is no more information

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

No - There is not 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

the project protocol will be reported after the end of the study

When the data will become available and for how long

Access time will be 6 moth after results publication

To whom data/document is available

All people without limitation

Under which criteria data/document could be used

any scientific usage

From where data/document is obtainable

Contact the project manager Dr. Tavakal Afshari with the following details. Address: Ferdowsi Square, Bo Ali Square, Mashhad, Bo Ali Research Institute, Department of Immunogenetics and Cell Culture Phone: 0517112674 tavakolaj@mums.ac.ir

What processes are involved for a request to access data/document

Send a written request by email to the project manager, Dr. Tavakal Afshari, with the mentioned address and contact number

Comments