Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Aug 2026

Safety and immuno-modulation evaluation of treatment with intravenous and spinal cord injections of of autologous mesenchymal stem cells in patients with amyotrophic lateral sclerosis (ALS).

Protocol summary

Study aim

Safety and immuno-modulation evaluation of treatment with intravenous and spinal cord injections of of autologous mesenchymal stem cells in patients with amyotrophic lateral sclerosis (ALS).

Design

Clinical trials without Contorol group , design for 13 patients.

Settings and conduct

Patients referred to clinics of Mashhad University of Medical Science and private sector visited by neurologist and by acquiring appreciation in case of having conditions, they will be enrolled.In Imam Reza Hospital of Mashhad the number 6-7 million MSC cell-derived Bone marrow in the form of Intrathechal (IT) and intravenous (IV) will be injected by a neurologist in the operating room and in completely sterile conditions to the patient . Before and after injection, patients will be evaluated in terms of immunological indices and clinical parameters.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with ALS certified by neurologist , Rated 31-46 ALSFRS-R score.Patients should have been treated with a fixed dose of Rilozule 3 months ago. Patients should have no other chronic detrimental disease and do not use ventilator. Exclusion criteria: Patients with Malignancy, Patients with other chronic disruptive diseases, pregnancy.

Intervention groups

Eligible patients will be received 6-7million MSC-derived Bone marrow in intravenous and intra-spinal injections by a professional healthcare . The number of injected cells will be equal in both methods.In addition to cell therapy, patient will receive other common treatments according to the specialist physician.

Main outcome variables

ALSFRS-R evaluation:Using standard questionnaires completed by neurologist. FVC measurement : Using Spirometry test. Evaluation of serum levels of IL-1β-1, TNF-α, IL-10, IFN-γ : using Elisa kits. Evaluation of TCD4 + CD25 + lymphocyte cells using flow cytometry technique

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160809029275N2**
Registration date: **2020-06-18, 1399/03/29**
Registration timing: **prospective**

Last update: **2020-06-18, 1399/03/29**
Update count: **0**

Registration date

2020-06-18, 1399/03/29

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

2020-06-21, 1399/04/01

Expected recruitment end date

2020-09-22, 1399/07/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Safety and immuno-modulation evaluation of treatment with intravenous and spinal cord injections of of autologous mesenchymal stem cells in patients with amyotrophic lateral sclerosis (ALS).

Public title
Stem cell therapy in ALS
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with ALS approved by neurologist with 31-46 ALSFRS-R score Patients should be treated with a fixed dose of Rilozule 3 months ago. Patients should not be detrimental to any other chronic disease and do not use ventilator.
Exclusion criteria:
Patients with malignancy Patients with other chronic disruptive diseases Pregnancy Others Neurodegenerative disease
Age
From **18 years** old to **75 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **15**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Mashhad University of Medical Science
Street address
Daneshgah Ave., Qureshi Building, Deputy of Research and Technology
City
Mashhad
Province
Razavi Khorasan
Postal code
9138813944
Approval date
2020-05-21, 1399/03/01
Ethics committee reference number
IR.MUMS.REC.1399.269

Health conditions studied

1

Description of health condition studied
Amyotrophic lateral sclerosis
ICD-10 code
G12.21
ICD-10 code description
Amyotrophic lateral sclerosis

Primary outcomes

1

Description
Earned score based on ALS-FRS test
Timepoint
Before, 1 and 3 months after injection of mesenchymal stem cells
Method of measurement
Standard Questionnaire

2

Description
Evaluation of serum levels of cytokines, IL-1 β, TNF-α, IL-10, IFN-γ
Timepoint
Before, 1 and 3 months after injection of mesenchymal stem cells
Method of measurement
Using Elisa method

3

Description
FVC measurement
Timepoint
Before, 1 and 3 months after injection of mesenchymal stem cells
Method of measurement
Using Spirometery test

4

Description
Evaluation of TCD4 + CD25 + lymphocyte cells.
Timepoint
Before, 1 and 3 months after injection of mesenchymal

stem cells

Method of measurement

Using Flowcytometery technique

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Group of receiving of Bone marroe-derived mesenchymal stem cells

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinics of Mashhad University of Medical sciences and private sector

Full name of responsible person

Dr.Amir Reza Borumand

Street address

Imam Reza Hospital, Imam Reza Sq., Ebne Sina Ave , Mashhad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

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

Mashhad University of Medical Sciences

Proportion provided by this source

60

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

2

Sponsor

Name of organization / entity

Knowledge-based company of Pooya Gostar Parnia Iranian

Full name of responsible person

Dr.Seyed Jalil Tavakol Afshari

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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

Knowledge-based company of Pooya Gostar Parnia Iranian

Proportion provided by this source

40

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
Other

Person responsible for general inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr.Seysd Jalil Tavakol Afshari
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Stem cell therapy
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Person responsible for updating data

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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
Undecided - It is not yet known if there will be a plan to make this available
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