

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 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 Control 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 Intrathecal (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 Riluzole 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-1 $\beta$ -1, TNF- $\alpha$ , IL-10, IFN- $\gamma$  : 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 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 Riluzole 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  $\beta$ , TNF- $\alpha$ , IL-10, IFN- $\gamma$

**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 Spirometry 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 Flowcytometry technique

#### Secondary outcomes

empty

#### Intervention groups

1

##### Description

Intervention group: Group of receiving of Bone marrow-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

###### City

Mashhad

###### Province

Razavi Khorasan

###### Postal code

9137913316

###### Phone

+98 51 3854 3031

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###### Email

IRH.p.relations@mums.ac.ir

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#### Sponsors / Funding sources

1

##### Sponsor

###### Name of organization / entity

Mashhad University of Medical Sciences

###### Full name of responsible person

Dr.Mohsen Tafaghodi

###### Street address

Qoreishi Building, Daneshgah Ave, Mashhad

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+98 51 3841 1538

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+98 51 3843 0249

##### Email

Vresearch@mums.ac.ir

##### 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

###### Street address

3rd Floor, Sadra Building, kafayi 1, Daneshgah Ave., Mashhad

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###### Province

Razavi Khorasan

###### Postal code

9196773117

###### Phone

+98 51 3848 2194

###### Email

Parnia@mums.ac.ir

##### 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

+98 51 3711 2610

**Fax**

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**Email**

Tavakolaj@mums.ac.ir

**Person responsible for general inquiries****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr.Seyd Jalil Tavakol Afshari

**Position**

Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Stem cell therapy

**Street address**

Bu-Ali Square,Bu-Ali Science and Technology Park,  
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**Person responsible for updating data****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

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**Position**

Professor

**Latest degree**

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**Other areas of specialty/work**

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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.Seyad Jalil Tavakol Afshari

**Position**

Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Stem cell therapy

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Razavi Khorasan

**Postal code**

9196773117

**Phone****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