

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Efficacy and safety of intrathecal injection of autologous mesenchymal stem cells in patients with amyotrophic lateral sclerosis (ALS)

Protocol summary

Study aim

In this study, investigators aimed to assess safety and efficacy of intrathecal injection of autologous mesenchymal stem cells in patients with Amyotrophic Lateral Sclerosis (ALS)

Design

Clinical trial without control group

Settings and conduct

Patients referred to neuromuscular clinic of Golestan hospital of Ahvaz are visited by a neurologist and patients with definite or probable ALS based on revised EL Escorial criteria will enter the study. All patients sign the informed consent prior to inclusion in the study. In Shafa hospital of Ahvaz bone marrow aspiration is performed and autologous mesenchymal stem cells are isolated. Patients are received bone marrow mesenchymal stem cells via lumbar puncture into the cerebrospinal fluid. Patients are monitored before and after treatment, potential adverse reactions are assessed, and the clinical outcome is evaluated by Revised ALS Functional Rating Scale (ALSFRS-R) and Forced Vital Capacity (FVC)

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients diagnosed as definite or probable ALS disease according to EL Escorial criteria, Time passed since onset of symptoms till inclusion be 3 years or less, ALSFRS-R score more than 26, FVC more than 40%, An age range of 25 to 70 years; Exclusion criteria: any major systemic disease, any coexisting neurodegenerative disease, pregnancy or lactation

Intervention groups

Eligible patients are received bone marrow mesenchymal stem cells via lumbar puncture into the cerebrospinal fluid.

Main outcome variables

ALSFRS-R evaluation: using standard questionnaires completed by neurologist. FVC measurement: using spirometry test

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200828048551N1**

Registration date: **2020-09-09, 1399/06/19**

Registration timing: **registered_while_recruiting**

Last update: **2020-09-09, 1399/06/19**

Update count: **0**

Registration date

2020-09-09, 1399/06/19

Registrant information

Name

Fatemeh Houshmand

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3374 3001

Email address

hooshmandf66@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-24, 1398/12/05

Expected recruitment end date

2020-09-26, 1399/07/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy and safety of intrathecal injection of autologous mesenchymal stem cells in patients with amyotrophic lateral sclerosis (ALS)		6135715794
Public title	Efficacy and safety of intrathecal injection of autologous mesenchymal stem cells in patients with amyotrophic lateral sclerosis (ALS)	Approval date 2020-02-22, 1398/12/03
Purpose	Treatment	Ethics committee reference number IR.AJUMS.REC.1398.904
Inclusion/Exclusion criteria	Inclusion criteria: Patients diagnosed as definite or probable ALS disease according to EL Escorial criteria ALSFRS-R more than 26 FVC more than 40% age 25-70 years Time passed since onset of the symptoms till inclusion be 3 years or less Exclusion criteria: Any major systemic disease Any coexisting neurodegenerative disease No other major pathology in brain or spinal cord pregnancy or lactation	Health conditions studied
Age	From 25 years old to 70 years old	<u>1</u> Description of health condition studied Amyotrophic lateral sclerosis
Gender	Both	ICD-10 code G12.21
Phase	2	ICD-10 code description Amyotrophic lateral sclerosis
Groups that have been masked	No information	Primary outcomes
Sample size	Target sample size: 10	<u>1</u> Description Disability
Randomization (investigator's opinion)	N/A	Timepoint 3 months
Randomization description		Method of measurement ALSFRS-R
Blinding (investigator's opinion)	Not blinded	<u>2</u> Description Forced vital capacity
Blinding description		Timepoint 3 months
Placebo	Not used	Method of measurement spirometry
Assignment	Single	<u>3</u> Description Side effects
Other design features		Timepoint 3 months
Secondary Ids	empty	Method of measurement Questionnaire
Ethics committees		Secondary outcomes empty
<u>1</u> Ethics committee		Intervention groups
Name of ethics committee	Ethics committee of Ahvaz University of Medical Sciences	<u>1</u> Description Intrathecal injection of mesenchymal stem cells
Street address	Ahvaz university of medical sciences, Farvardin Ave, Ahvaz	Category Treatment - Other
City	Ahvaz	Recruitment centers
Province	Khouzestan	
Postal code		

1

Recruitment center

Name of recruitment center

Golestan hospital

Full name of responsible person

Fatemeh Houshmand

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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

Ahvaz 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**

Ahvaz University of Medical Sciences

Full name of responsible person

Dr Gholamreza Shamsaei

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Neurology

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Person responsible for updating data

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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

Sharing plan**Deidentified Individual Participant Data Set (IPD)**