

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Aug 2026

Evaluation of safety and efficacy of repeated intrathecal and/or intravenous transplantations of Wharton's jelly derived mesenchymal stromal cells in patients with ALS, clinical trial, phase I

Protocol summary

Study aim

Evaluation of safety and efficacy of repeated intrathecal and/or intravenous transplantations of Wharton's jelly derived mesenchymal stromal cells in patients with ALS

Design

This study, which is a phase 1 clinical trial, includes 12 patients with ALS.

Settings and conduct

The patient was admitted to the VIP room of Mostafa Khomeini Hospital and the cell suspension prepared from Whartocell allogeneic cell bank produced in the center with good manufacturing products (GMP) grade was injected intrathecally by the neurologist in charge of the project in 6 patients and intravenously by the expert nurse in charge in 6 other patients.

Participants/Inclusion and exclusion criteria

Age: 18-70 Both gender Disease onset at least: 6 months
All patients diagnosed with ALS and R/O of differential diagnosis Forced Vital Capacity (FVC) $\geq 40\%$ ALS
Functional Rating Scale-Revised (ALSFRS-R) ≥ 25 Under treatment with riluzole and edaravone Ability to walk even with aid and ability to tolerate the procedures

Intervention groups

1- Intrathecal transplantations of Wharton's jelly derived mesenchymal stromal cells 2- Intravenous transplantations of Wharton's jelly derived mesenchymal stromal cells

Main outcome variables

1- Evaluation of possible side effects after repeated intrathecal transplantation or Intravenous allogeneic cord-derived mesenchymal cells of allogeneic cord in patients with ALS 2- Evaluation of changes in ALSFRS-R score 3- Evaluation of FVC changes 4- Evaluation of year survival

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20080728001031N32**

Registration date: **2022-05-07, 1401/02/17**

Registration timing: **prospective**

Last update: **2022-05-07, 1401/02/17**

Update count: **0**

Registration date

2022-05-07, 1401/02/17

Registrant information

Name

Nasser Aghdami

Name of organization / entity

Royan Institute

Country

Iran (Islamic Republic of)

Phone

+98 21 2356 2000

Email address

nasser.aghdami@royaninstitute.org

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-20, 1401/02/30

Expected recruitment end date

2022-07-06, 1401/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	
Scientific title Evaluation of safety and efficacy of repeated intrathecal and/or intravenous transplantations of Wharton's jelly derived mesenchymal stromal cells in patients with ALS, clinical trial, phase I	Street address Royan Institute, Banihashem Sq., Banihashem St., Ghasem Soleimani highway, Tehran, Iran
Public title Evaluation of safety and effectiveness of recurrent umbilical cord-derived stem cell transplantation in patients with ALS	City Tehran
Purpose Treatment	Province Tehran
Inclusion/Exclusion criteria Inclusion criteria: Age: 18-70 Both gender Disease onset at least: 6 months All patients diagnosed with ALS and R/O of differential diagnosis FVC ≥40% ALSFRS-R ≥ 25 Under treatment with riluzole and edaravone Ability to walk even with aid and ability to tolerate the procedures Exclusion criteria: Concomitant psychiatric or cognitive disease Concomitant systemic disease (uncontrolled HTN, uncontrolled DM, uncontrolled kidney diseases, HF, ...) Treatment with corticosteroid , IVIg, immunosuppressive and cytotoxic during 12 months Dependency to ventilation History of malignancy Concomitant other neurodegenerative disorders	Postal code 19395-4644
Age From 18 years old to 70 years old	Approval date 2022-03-13, 1400/12/22
Gender Both	Ethics committee reference number IR.ACECR.ROYAN.REC.1400.169
Phase 1	
Groups that have been masked No information	
Sample size Target sample size: 12	
Randomization (investigator's opinion) N/A	
Randomization description	
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 Medicel Ethics committee of Royan institute	Health conditions studied 1 Description of health condition studied Amyotrophic lateral sclerosis (ALS) ICD-10 code G12.21 ICD-10 code description Amyotrophic lateral sclerosis Primary outcomes 1 Description safety Timepoint Evaluation of possible side effects at intervals of 24 hours, 1 month, 3 months, 6 and 12 months after injection Method of measurement side effects questionnaire Secondary outcomes 1 Description Changes in ALSFRS-R score Timepoint 1, 3, 6 and 12 months after transplantation Method of measurement ALSFRS-R questionnaire 2 Description Changes in FVC percent (spirometry) Timepoint 6 and 12 months after transplantation Method of measurement Spirometry 3 Description One-year survival

Timepoint

one year

Method of measurement

visiting the patients

Intervention groups**1****Description**

Intervention groups: Intravenous or intrathecal injection of 60 millions of Wharton's jelly derived mesenchymal stromal cells in two doses/ 3 months- WJMSCs are suspended in 10 ml N/S for intravenous and 5 ml for intrathecal transplantation. Celltech pharmed Co. provided the WJMSCs for this study.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Royan Research Institute Neurology Clinic

Full name of responsible person

Seyed Massood Nabavi

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Celltech Pharmed Co.

Full name of responsible person

Mohammad Hossein Ziraksaz

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CellTech Pharmed Company, Toalidaroo Factory,
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Email

Ziraksaz@celltech.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Celltech Pharmed Co.

Proportion provided by this source

90

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**

Industry

2**Sponsor****Name of organization / entity**

Royan Stem Cell Technology Co.

Full name of responsible person

Morteza Zarrabi

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Royan Institute, Banihashem Sq., Banihashem St.,
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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

Royan Stem Cell Technology Co.

Proportion provided by this source

10

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**

Industry

Person responsible for general inquiries

Contact

Name of organization / entity

Royan Research Institute

Full name of responsible person

Hoda Madani

Position

Researcher

Latest degree

Medical doctor

Other areas of specialty/work

Others

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Person responsible for scientific inquiries

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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

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable