Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the therapeutic efficiency of the placenta mesenchymal stem cell-derived exosomes on the improvement of interstitial lung disease symptoms in systemic sclerosis patients, a single-arm trial.

Protocol summary

Study aim

Evaluation of the therapeutic efficiency of the placenta mesenchymal stem cell-derived exosomes on the improvement of interstitial lung disease symptoms in systemic sclerosis patients

Design

This is a single-blinded clinical trial. In this single-blinded study, participants were kept blind to the exosome dose. This randomized study will be performed on 10 patients with systemic sclerosis with severe pulmonary fibrosis.

Settings and conduct

This single-blinded study will be performed in Imam Reza hospital of Kermanshah. Due to the systemic nature of the disease process, the involvement of pulmonary fibrosis is generally bilateral and not unilateral, and in this plan, the opinion and radiologist report is the criterion for determining the severity of pulmonary fibrosis and quantification.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Informed consent; American College of Rheumatology (ACR) and EULAR2013 diagnostic criteria for systemic sclerosis Intestinal lung disease confirmed by chest CT scan and lung function tests Exclusion criteria: Suffering from other autoimmune diseases; Uncontrolled high blood pressure, diabetes and other endocrine disorders; Cardiovascular failure; Hepatic impairment; Existence of life-threatening conflicts including severe platelet hemolysis below 40,000; Pregnancy and lactation

Intervention groups

In addition to standard treatment (cyclophosphamide and mycophenolate mofetil), the intervention group will receive exosomes derived from placenta mesenchymal stem cells in three sessions two weeks apart.

Main outcome variables

Rate of pulmonary involvement

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130812014333N184**
Registration date: **2022-04-16, 1401/01/27**
Registration timing: **prospective**

Last update: **2022-04-16, 1401/01/27**
Update count: **0**

Registration date

2022-04-16, 1401/01/27

Registrant information

Name

Feizollah Foroughi

Name of organization / entity

kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-18, 1401/01/29

Expected recruitment end date

2022-07-20, 1401/04/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluation of the therapeutic efficiency of the placenta mesenchymal stem cell-derived exosomes on the improvement of interstitial lung disease symptoms in systemic sclerosis patients, a single-arm trial.

Public title
Evaluation of the therapeutic efficiency of the placenta mesenchymal stem cell-derived exosomes on the improvement of interstitial lung

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Informed consent American College of Rheumatology (ACR) and EULAR2013 diagnostic criteria for systemic sclerosis Intestinal lung disease confirmed by chest CT scan and lung function tests

Exclusion criteria:
Suffering from other autoimmune diseases Uncontrolled high blood pressure, diabetes, and other endocrine disorders Cardiovascular failure Chronic renal failure Hepatic impairment Depression Existence of life-threatening conflicts including severe platelet hemolysis below 40,000 Pregnancy and lactation

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **10**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description
Participants are kept blind to the dose of exosomes they receive

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Kermanshah University of Medical Sciences

Street address
Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti Boulevard

City
Kermanshah

Province
Kermanshah

Postal code
6715847141

Approval date
2022-01-10, 1400/10/20

Ethics committee reference number
IR.KUMS.REC.1400.794

Health conditions studied

1

Description of health condition studied
systemic sclerosis (scleroderma)

ICD-10 code
M34

ICD-10 code description
Systemic sclerosis [scleroderma]

Primary outcomes

1

Description
Rate of pulmonary involvement

Timepoint
Before and after the intervention (4-6 weeks later)

Method of measurement
Using CT scan

Secondary outcomes

empty

Intervention groups

1

Description
In addition to standard treatment (cyclophosphamide and mycophenolate mofetil), the intervention group will receive exosomes derived from placenta mesenchymal stem cells in three sessions two weeks apart.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza Hospital
Full name of responsible person
Dena Mohamadzadeh
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Kermanshah 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
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Person responsible for updating data

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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
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available