# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

29 Jun 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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+98 83 1821 4653

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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

**Street address**
Emam Reza Hospital, Parastar Boulevard

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denamohamadzadeh75@gmail.com

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**
Kermanshah University of Medical Sciences

**Full name of responsible person**
Dr. Reza Khodarahmi

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

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rkhodarahmi@kums.ac.ir

**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**
Kermanshah University of Medical Sciences

**Full name of responsible person**
Dena Mohamadzadeh

**Position**
Resident of Internal

**Latest degree**
Medical doctor

**Other areas of specialty/work**
Internal Medicine

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## Person responsible for scientific inquiries

**Contact**

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Kermanshah University of Medical Sciences

**Full name of responsible person**
Dr. Shirin Asar

**Position**
Faculty member of Kermanshah University of Medical Sciences

**Latest degree**
Subspecialist

**Other areas of specialty/work**
Rheumatology

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## Person responsible for updating data

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**Latest degree**
Medical doctor

**Other areas of specialty/work**

Internal Medicine

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**Email**

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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