# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 2026

## The therapeutic efficiency and immunogenic assessments of the placenta mesenchymal stem cell–derived exosomes on alleviation of symptoms in patients with lupus (a clinical trials)

## Protocol summary

**Study aim**
Efficacy and safety of exosomes derived from placenta mesenchymal stem cells in improving the symptoms of patients with lupus

**Design**
This is a randomized clinical trial design with a parallel design, with the control group and not blinded. This study randomized, phase 2-3 study will be performed on 20 patients with lupus. Random blocks are used for randomization and participants are assigned to two intervention and control groups .

**Settings and conduct**
This study, which will be performed at the Kermanshah Biological Research Center, is not blinded. Researchers and participants have no role in the process of randomization and assignment of intervention and control groups. Data collection will be done by a rheumatologist. The patient's clinical and laboratory signs are recorded in a checklist.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: Informed consent; Class 3 or 4 resistant lupus nephritis; Parenchymal lung involvement or refractory heart involvement; Resistant vasculitis; Resistant CNS involvement Exclusion criteria: Other autoimmune diseases; Severe renal failure and need to dialysis; Uncontrolled high blood pressure; diabetes and other endocrine disorders

**Intervention groups**
The intervention group will receive the conventional treatment with exosomes derived from a single source of placenta mesenchymal stem cells (first one-tenth of the mesenchymal exosomes are injected. If no side effects are observed within two days, the unit values are gradually increased within two weeks, up to 4 units will be given intravenously). The control group will receive only the usual treatment.

**Main outcome variables**
Anti-nuclear antibodies, anti-phospholipid antibodies, metabolic panel

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20130812014333N182**
Registration date: **2022-02-16, 1400/11/27**
Registration timing: **registered_while_recruiting**

Last update: **2022-02-16, 1400/11/27**
Update count: **0**

**Registration date**
2022-02-16, 1400/11/27

**Registrant information**

**Name**
Feizollah Foroughi

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

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Iran (Islamic Republic of)

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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2022-02-09, 1400/11/20

**Expected recruitment end date**
2022-08-11, 1401/05/20

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
The therapeutic efficiency and immunogenic assessments of the placenta mesenchymal stem cell–derived exosomes on alleviation of symptoms in patients with lupus (a clinical trials)

**Public title**
Efficacy stem cells in improving the symptoms of patients with lupus
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Class 3 or 4 resistant lupus nephritis Parenchymal lung involvement or refractory heart involvement Resistant vasculitis Resistant CNS involvement
**Exclusion criteria:**
Other autoimmune diseases Uncontrolled high blood pressure Diabetes and other endocrine disorders Cardiovascular failure Severe renal failure and need to dialysis Hepatic impairment Depression Endocarditis Lupus pneumonia Pregnancy and breast-feeding
**Age**
No age limit
**Gender**
Both

**Phase**
2-3
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **20**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
Using block randomization method with 4 blocks (5 blocks of 4). A random sequence will be created by an epidemiologist using the site https://www.sealedenvelope.com.
**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**
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**
2021-06-08, 1400/03/18
**Ethics committee reference number**
IR.KUMS.REC.1400.198

## Health conditions studied

**1**

**Description of health condition studied**
Systemic lupus erythematosus
**ICD-10 code**
M32
**ICD-10 code description**
Systemic lupus erythematosus (SLE)

## Primary outcomes

**1**

**Description**
Anti-Nuclear Antibody (ANA)
**Timepoint**
2 to 3 days after injection every 6 to 8 weeks
**Method of measurement**
Taking blood from the arm area

**2**

**Description**
Antiphospholipid antibodies
**Timepoint**
2 to 3 days after injection every 6 to 8 weeks
**Method of measurement**
In the laboratory with a blood test

**3**

**Description**
Glucose
**Timepoint**
2 to 3 days after injection every 6 to 8 weeks
**Method of measurement**
In the laboratory with a blood test

**4**

**Description**
triglyceride

**Timepoint**
2 to 3 days after injection every 6 to 8 weeks
**Method of measurement**
In the laboratory with a blood test

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
The intervention group will receive the conventional treatment(Such as hydroxychloroquine) with exosomes derived from a single source of placenta mesenchymal stem cells (first one-tenth of the mesenchymal exosomes are injected. If no side effects are observed within two days, the unit values are gradually increased within two weeks, up to 4 units will be given intravenously).
**Category**
Treatment - Other

### 2

**Description**
The control group will receive only the usual treatment (Such as hydroxychloroquine).
**Category**
Treatment - Other

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Medical Biology Research Center
**Full name of responsible person**
Shima Famil Samavati
**Street address**
Medical Biology Research Center, Parasta Boulevard
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## 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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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**
Shima Famol Samavati
**Position**
PhD student in Biochemistry
**Latest degree**
Master
**Other areas of specialty/work**
Biochemistry
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## Person responsible for scientific inquiries

**Contact**

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**Full name of responsible person**
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Faculty member of Kermanshah University of Medical Sciences

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## Person responsible for updating data

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**Latest degree**
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**Other areas of specialty/work**
Biochemistry

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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