

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 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

Country

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

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

Kermanshah University of Medical Sciences

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

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

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Kamran Mansouri

Position

Faculty member of Kermanshah University of Medical Sciences

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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