

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 2026

Evaluating the Safety and Effect of Allogeneic Adipose Tissue-Derived Mesenchymal Stem Cell Transplantation on Development of Renal Function Indexes in Patients with Severe and Refractory Lupus Nephritis in Comparison to the Standard Treatment Protocol

Protocol summary

Summary

In the present study, we analyze safety and effects of allogeneic adipose-derived mesenchymal stem cell transplantation into patients with refractory lupus nephritis, who have acquired resistance to conventional treatment regimens in order to introduce a new approach for treatment of Lupus. This controlled interventional study will be performed on 20 patients with lupus nephritis from whom 10 people will be considered as controls. For interventional group, adipose-derived mesenchymal stem cell will be isolated from adipose tissue of healthy donors between the ages of 18 and 40 years, who had no history of any significant illness and had no physical or mental disability, are selected from members of the patient's families with HLA matching. The consents are obtained from all patients. Criteria for entrance to the study include decrease in renal function, increase in protein urine (defined as more than 1.0 g of protein excretion in a 24-h urine specimen), Systemic lupus erythematosus disease activity index score of more than 8 (All patients were resistant to at least 3 months of therapy with conventional treatment standard). The exclusion criteria also, involve uncontrolled infection, failure of kidney or other vital organs and so forth. Allogeneic Ad-MSCs are transplanted intravenously at the dose of 2 million cells/kilogram of body weight. All patients are then followed up over the course of 18 months (after a week, one, three, six, twelve and eighteen months) to evaluate renal remission, as well as possible side effects. The patients are evaluated before and after transplantation for clinical changes using the Systemic lupus erythematosus disease activity index and assessment renal function (Glomerular filtration rate, Proteinuria).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016090729747N1**

Registration date: **2017-06-03, 1396/03/13**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-06-03, 1396/03/13

Registrant information

Name

Maryam Moghaddam Matin

Name of organization / entity

Ferdowsi University of Mashhad

Country

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Recruitment status

Recruitment complete

Funding source

council for stem cell sciences and technologies, Iranian academic center for education, culture and research (ACECR), Mashhad, ferdowsi university of mashhad.

Expected recruitment start date

2016-07-22, 1395/05/01

Expected recruitment end date

2017-07-23, 1396/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the Safety and Effect of Allogeneic Adipose Tissue-Derived Mesenchymal Stem Cell Transplantation on Development of Renal Function Indexes in Patients with Severe and Refractory Lupus Nephritis in Comparison to the Standard Treatment Protocol

Public title

Effect of Allogeneic Adipose Tissue-Derived Mesenchymal Stem Cell Transplantation on SLE

Purpose

Treatment

Inclusion/Exclusion criteria

Criteria for entrance to the study: Criteria for entrance to the study include increase in proteinuria (defined as more than 1.0 g of protein excretion in a 24-h urine specimen), Systemic lupus erythematosus disease activity index of more than 8 (All patients were resistant to at least 3 months of therapy with conventional treatment standard). Exclusion criteria: uncontrolled infection, failure of kidney or other vital organs, pregnancy or lactating.

Age

No age limit

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

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**

Iran ACECR Biomedical Research Ethics Committee

Street address

Enghelab St., Tehran, Iran

City

Tehran

Postal code**Approval date**

2016-12-11, 1395/09/21

Ethics committee reference number

IR.ACECR.REC.1395.3

Health conditions studied**1****Description of health condition studied**

Severe and Refractory Lupus Nephritis

ICD-10 code

M32.1

ICD-10 code description

Systemic lupus erythematosus with organ or system involvement

Primary outcomes**1****Description**

proteinuria

Timepoint

1 week, 1, 3, 6, 9 and 12 months

Method of measurement

clinical tests

2**Description**

Glomerular filtration rate

Timepoint

1 week, 1, 3, 6, 9 and 12 months

Method of measurement

clinical tests

Secondary outcomes**1****Description**

Systemic lupus erythematosus disease activity index score

Timepoint

1 week, 1, 3, 6, 12 and 18 months

Method of measurement

clinical tests

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

Intervention group: systemic (intravenous) transplantation of Adipose-derived Mesenchymal Stem Cell to patient (2 millions/Kg).

Category

Treatment - Other

2

Description

control group: No cell transplantation with conventional treatment regimens

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Educational, Research and Treatment Center

Full name of responsible person

Street address

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Council for Stem Cell Sciences and Technologies

Full name of responsible person

Dr. Amirali Hamidieh

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No 20, Ladan Alley, Mollasadra St., Vanak Sq., Tehran, Iran

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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

Council for Stem Cell Sciences and Technologies

Proportion provided by this source

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

2

Sponsor

Name of organization / entity

Iranian Academic Center for Education, Culture and Research (ACECR), Khorasan Razavi Branch, Mashhad

Full name of responsible person

Dr. Hamidreza Bidkhori

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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

Iranian Academic Center for Education, Culture and Research (ACECR), Khorasan Razavi Branch, Mashhad

Proportion provided by this source

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

3

Sponsor

Name of organization / entity

Ferdowsi Uiniversity of Mashhad

Full name of responsible person

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Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ferdowsi Uiniversity of Mashhad

Proportion provided by this source

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Department of Internal Medicine, Mashhad University of Medical Sciences

Full name of responsible person

Zhaleh Shariati-Sarabi

Position

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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Full name of responsible person

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Position

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Full name of responsible person

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Position

Ph.D student of cell and molecular biology/Member of Stem Cell and Regenerative Medicine Research Gr

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty