Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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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 Commitee
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
Street address
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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Grant code / Reference number
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

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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