# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 Jun 2026

## Adult Human Mesenchymal Stem Cells for the treatment of Steroid-Refractory Acute Graft-versus-Host Disease

## Protocol summary

**Summary**

1- Objectives, Investigation on adult human mesenchymal stem cell transplantation on treatment of steroid-refractory acute graft-versus-host disease 2- Design, the study is designed as a phase 1-2, parallel, open-label, single-centric randomized clinical trial. In the beginning, among patients with acute graft-versus-host disease who eligible for inclusion criteria for cell therapy, ten patients as recipients and ten patients as control will be selected. 3- Setting and conduct, All stages of the project explain for each patients as recipient and healthy volunteers as donor, then if they want to enter the project inform consent would be obtained. Then, mesenchymal stem cells (MSCs) obtained via donors bone marrow aspiration would be cultured. After propagation of the cells, each patient will receive MSCs intravenously. Patients will be examined and visited by medical team on 1st, 4th, 7th, 14th, 21th, 28th days and six months after cell therapy and clinical and para-clinical indexes of patients will be assessed. 4- Participants including major eligibility criteria, steroid-refractory acute graft-versus-host disease with grade II to IV. 5- Intervention, Each patient will receive 1 million MSCs /kg by IV injection. 6- Main outcome measures (variables), Include assessing the efficacy of treatment by graft-versus-host disease clinical grading, acute and late onset side effects of mesenchymal stem cell therapy.

## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT2014072618603N1**
Registration date: **2015-10-26, 1394/08/04**
Registration timing: **prospective**

Last update:
Update count: **0**

**Registration date**

2015-10-26, 1394/08/04

**Registrant information**

**Name**
Fatemeh Amirmoezi
**Name of organization / entity**
Hematology research center/SUMS
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Iran (Islamic Republic of)
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**Recruitment status**

**Recruitment complete**

**Funding source**

Shiraz University of Medical Sciencecs

**Expected recruitment start date**

2016-04-20, 1395/02/01

**Expected recruitment end date**

2016-12-21, 1395/10/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Adult Human Mesenchymal Stem Cells for the treatment of Steroid-Refractory Acute Graft-versus-Host Disease

**Public title**

Adult Human Mesenchymal Stem Cells for the treatment of Steroid-Refractory Acute Graft-versus-Host Disease

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: recipients of allogeneic hematopoietic stem cell transplantation; patients with refractory acute graft versus host disease; subjects (or their legally acceptable representatives) must have signed an informed consent document indicating that they understand the purpose of and procedures required for the study and are willing to participate in the study
Exclusion criteria: any abnormality in a vital sign (heart rate, respiratory rate, or blood pressure); patients with any conditions not suitable for the trial (investigators' decision)

**Age**
From **2 years** old to **60 years** old

**Gender**
Both

**Phase**
3

**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**
Ethics committee of Shiraz University of Medical Sciences

**Street address**
7th floor, Vice chancellery for research affairs, Shiraz University of Medical Sciences, Zand avenue, Shiaz, Iran

**City**
Shiraz

**Postal code**

**Approval date**
2015-09-05, 1394/06/14

**Ethics committee reference number**
IR.SUMS.REC.1394.97

## Health conditions studied

**1**

**Description of health condition studied**
Graft-versus-host reaction or disease

**ICD-10 code**
T86.0

**ICD-10 code description**
Graft-versus-host reaction or disease

## Primary outcomes

**1**

**Description**
The efficacy of treatment for refractory acute graft versus host disease

**Timepoint**
1, 4, 7, 14, 21, 28 days and 6 months after end of treatment

**Method of measurement**
The response criteria include complete response, part response, stable disease and progressive disease. complete response: acute graft versus host disease symptoms and signs disappear; part response: acute graft versus host disease symptoms and signs improve; stable disease: acute graft versus host disease symptoms and signs remain (without improvement or deterioration); progressive disease: acute graft versus host disease symptoms and signs deteriorate

## Secondary outcomes

**1**

**Description**
Acute toxic side effects of mesenchymal stem cells treatment

**Timepoint**
1, 4, 7, 14, 21, 28 days after end of the treatment

**Method of measurement**
To asses acute toxicity principally involves the heart, liver and kidney and possible infections by clinical presentation and paraclinical evaluations

**2**

**Description**
Late toxic side effects of mesenchymal stem cells treatment

**Timepoint**
6 months after end of the treatment

**Method of measurement**
To asses late toxic side effects involves principally the development of secondary tumors, relapse of the primary disease and chronic graft versus host disease during 6 months of study by clinical presentation and paraclinical evaluations.

## Intervention groups

**1**

**Description**
Intervention group: Patients who receive standard of care plus intravenous injection of 1 ± 0.5 × 106 cells/ kg recipient body weight of allogenic adult human mesenchymal stem cell
**Category**
Treatment - Other

**2**

**Description**
Control group: Patients who just receive standard of care include steroid therapy such as methylprednisolone 2 mg/kg daily.
**Category**
Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Namazi hospital, Shiaz University of Medical Sciences, Shiraz, Iran
**Full name of responsible person**
Dr. Reza Vojdani
**Street address**
**City**
Shiraz

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Vice chancellor of research, Shiaz Univeisity of Medical Sciences
**Full name of responsible person**
Dr. Seyed Basir Hashemi
**Street address**
7th floor, Shiraz University of Medical Sciences, Zand avenue, Shiraz, Iran
**City**
Shiraz
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Vice chancellor of research, Shiaz Univeisity of Medical Sciences
**Proportion provided by this source**
100
**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**
Institute of Hematology -Oncology, Nemazee Hospital, Shiraz, Iran
**Full name of responsible person**
Dr. Reza Vojdani
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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*