

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

Evaluation of Mesenchymal stem cell therapy effects on the cellular immune response in refractory rheumatoid arthritis patients

Protocol summary

Study aim

Evaluation of mesenchymal stem cell therapy effects on cellular immune response in refractory rheumatoid arthritis patients.

Design

This study is a single-arm clinical trial in which a single intravenous dose of autologous bone marrow derived mesenchymal stem cells will be administered to 21 patients with refractory rheumatoid arthritis.

Settings and conduct

Autologous bone marrow derived mesenchymal stem cells will be obtained by bone marrow aspiration and will be cultured in Minimum Essential Medium-Alpha for 4 weeks in standard clean room and then transfused to RA patients intravenously.

Participants/Inclusion and exclusion criteria

Twenty one refractory rheumatoid arthritis patients who show resistance to non biological DMARDs after 6 to 12 months will be enrolled in this study. Non-resistant RA patients to non-biological DMARDs will not be enrolled in this study.

Intervention groups

A single intravenous administration of autologous bone marrow derived mesenchymal stem cells (2000000 to 3000000 cells/Kg) to refractory rheumatoid arthritis patients with resistance to non-biological DMARDs

Main outcome variables

Finding of mesenchymal stem cell therapy effects on the cellular immune responses.

General information

Reason for update

To correct the ethics committee reference number.

Acronym

IRCT registration information

IRCT registration number: **IRCT2015102824760N1**

Registration date: **2016-06-12, 1395/03/23**

Registration timing: **prospective**

Last update: **2023-08-12, 1402/05/21**

Update count: **2**

Registration date

2016-06-12, 1395/03/23

Registrant information

Name

Mojgan Mohammadi

Name of organization / entity

Mashhad University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Research Chancellor, Mashhad University of Medical Sciences Council for Stem Cell Sciences and Technologies, Presidency of the Islamic Republic of Iran, Vice presidency for Science and Technology

Expected recruitment start date

2016-06-19, 1395/03/30

Expected recruitment end date

2018-06-20, 1397/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Mesenchymal stem cell therapy effects on the cellular immune response in refractory rheumatoid arthritis patients

Public title

Evaluation of Mesenchymal stem cell therapy effects on the cellular immune response in refractory rheumatoid arthritis patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Resistant RA patients to non-biological DMARDs
Treated RA patients by non-biological drugs
Treated RA patients by Prednisolone, Hydroxychloroquine, Sulfasalazine and Methotrexate
Patients aged between 35-60 years
Refractory RA patients with no other rheumatologic disorders and inflammatory diseases

Exclusion criteria:

Non-resistant RA patients to non-biological DMARDs

Age

From **35 years** old to **60 years** old

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **21**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Qoreishi Bulding, Daneshgah St

City

Mashhad

Province

Razavi Khorasan

Postal code

91375-345

Approval date

2015-11-21, 1394/08/30

Ethics committee reference number

IR.MUMS.REC.1394.529

2

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

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Postal code

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Approval date

2023-05-20, 1402/02/30

Ethics committee reference number

IR.MUMS.REC.1402.076

Health conditions studied

1

Description of health condition studied

Rheumatoid arthritis

ICD-10 code

M05

ICD-10 code description

Diseases of the musculoskeletal system and connective tissue

Primary outcomes

1

Description

Interleukin-1

Timepoint

Before intervention and after 1, 6, 12 months follow up

Method of measurement

pg/ml using ELISA assay

2

Description

TNF-alpha

Timepoint

Before intervention and after 1, 6, 12 months follow up

Method of measurement

pg/ml using ELISA assay

3

Description

Interleukin-4

Timepoint

Before intervention and after 1, 6, 12 months follow up

Method of measurement

pg/ml using ELISA assay

4

Description

Interleukin-10

Timepoint

Before intervention and after 1, 6, 12 months follow up

Method of measurement

pg/ml using ELISA assay

5

Description

TGF-beta

Timepoint

Before intervention and after 1, 6, 12 months follow up

Method of measurement

Frequency and the intensity of stained cells in the ELISPOT assay

6

Description

Interleukin-17

Timepoint

Before intervention and after 1, 6, 12 months follow up

Method of measurement

pg/ml using ELISA assay

7

Description

T-bet transcription factor

Timepoint

Before intervention and after 1, 6, 12 months follow up

Method of measurement

The copy number of desired gene using RT-PCR assay

8

Description

GATA3 transcription factor

Timepoint

Before intervention and after 1, 6, 12 months follow up

Method of measurement

The copy number of desired gene using RT-PCR assay

9

Description

FOXP3 transcription factor

Timepoint

Before intervention and after 1, 6, 12 months follow up

Method of measurement

The copy number of desired gene using RT-PCR assay

10

Description

ROR-gamma T transcription factor

Timepoint

Before intervention and after 1, 6, 12 months follow up

Method of measurement

The copy number of desired gene using RT-PCR assay

11

Description

T helper cells

Timepoint

Before intervention and after 1, 6, 12 months follow up

Method of measurement

Frequency of desired cells using flow cytometry technique

12

Description

Regulatory T cells

Timepoint

Before intervention and after 1, 6, 12 months follow up

Method of measurement

Frequency of desired cells using flow cytometry technique

13

Description

Th17

Timepoint

Before intervention and after 1, 6, 12 months follow up

Method of measurement

Frequency of desired cells using flow cytometry technique

14

Description

Disease activity score (DAS)

Timepoint

Before intervention and after 1, 6, 12 months follow up

Method of measurement

Clinical and laboratory findings

15

Description

Visual analogue scale (VAS)

Timepoint

Before intervention and after 1, 6, 12 months follow up

Method of measurement

The amount of pain that a patient feels

16

Description

Erythrocyte sedimentation rate(ESR)

Timepoint

Before intervention and after 1, 6, 12 months follow up

Method of measurement

Erythrocyte sedimentation rate in millimeters

17

Description

C-reactive protein (CRP)

Timepoint

Before intervention and after 1, 6, 12 months follow up

Method of measurement

Latex agglutination test

18

Description

Rheumatoid factor(RF)

Timepoint

Before intervention and after 1, 6, 12 months follow up

Method of measurement

Latex agglutination test

19

Description

Anti-cyclic citrullinated peptide (anti-CCP)

Timepoint

Before intervention and after 1, 6, 12 months follow up

Method of measurement

ELISA test

20

Description

TNF- α

Timepoint

Before intervention and after 1, 6, 12 months follow up

Method of measurement

The copy number of desired gene using RT-PCR assay

21

Description

IL-17A

Timepoint

Before intervention and after 1, 6, 12 months follow up

Method of measurement

The copy number of desired gene using RT-PCR assay

Secondary outcomes

1

Description

Anaphylaxis

Timepoint

After IV infusion of MSCs

Method of measurement

Clinical manifestations, hypotension and hypoglycemia

2

Description

Differentiation of MSCs to unwanted cells

Timepoint

After IV infusion of MSCs

Method of measurement

Clinical manifestations

Intervention groups

1

Description

A single intravenous administration of autologous bone marrow derived mesenchymal stem cells(2000000 to 3000000 cells/Kg).

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza Hospital

Full name of responsible person

Dr. Zhale shariati sarabi

Street address

Ebne Sina Ave, Emam Reza Sq

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Chancellor, Mashhad University of Medical Sciences

Full name of responsible person

Dr. Mojgan Mohammadi

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Mohammadimzh@mums.ac.ir

Grant name

Grant code / Reference number

931523

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

Yes

Title of funding source

Research Chancellor, Mashhad University of Medical Sciences

Proportion provided by this source

75

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

2**Sponsor****Name of organization / entity**Council for Stem Cell Sciences and Technologies,
Presidency of the Islamic Republic of Iran, Vice pr**Full name of responsible person**

Dr. Amir Ali Hamidieh

Street addressNo 21, Ladan Alley, North Sheikh Bahayee St,
MollaSadra St, Vanak Sq**City**

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Grant name**Grant code / Reference number**

122

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

Yes

Title of funding sourceCouncil for Stem Cell Sciences and Technologies,
Presidency of the Islamic Republic of Iran, Vice pr**Proportion provided by this source**

25

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**

Other

Person responsible for general inquiries**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Ghoryani

Position

Ph.D in Immunology

Latest degree

Ph.D.

Other areas of specialty/work**Street address**

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

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Position

Ph.D

Latest degree

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Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

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Latest degree

Ph.D.

Other areas of specialty/work

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

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available