Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 administred to 21 patinets 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
Iran (Islamic Republic of)

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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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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
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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 address
No 21, Ladan Alley, North Sheikh Bahayee St, MollaSadra St, Vanak Sq
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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 source
Council 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
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Person responsible for updating data

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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