

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

Evaluation of the effect of autologous adipose derived stem cells stromal vascular fraction (SVF) on the treatment of generalized plaque psoriasis

Protocol summary

Study aim

Evaluation of the effect of autologous adipose derived stem cells stromal vascular fraction (SVF) on the treatment of generalized plaque psoriasis

Design

Before-after interventional clinical trial, without control group using availability sampling, performed on 5 patients with plaque psoriasis.

Settings and conduct

This study is performed on 5 patients with generalized plaque psoriasis referring to Ghaem and Imam Reza Hospitals of Mashhad who have Psoriasis Area and Severity Index (PASI) of more than 10 and have not used systemic drugs for psoriasis for any reasons within the last three months. Patients are selected using availability sampling and will be subjected to venous infusion of autologous SVF twice at intervals of one month. Then, patients will be examined during the first month after treatment, weekly for up to 1 month, and then monthly for up to 6 months.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Body Mass Index value of 18 to 25, Generalized plaque psoriasis based on Psoriasis Area and Severity Index (PASI) of more than 10 or based on more than 10% body involvement Exclusion criteria: coagulation disorder, heart, lung, kidney, liver diseases and malignancy, contraindication for liposuction, active infections including HIV, HCV, HBV, HTLV1, absence of mental health

Intervention groups

Intervention group: Patients are subjected to venous infusion of autologous adipose derived stem cells stromal vascular fraction (SVF) twice at intervals of one month. Each time, after an aspiration of 100 cc of adipose tissue, the achieved autologous SVF is injected intravenously into the patients' forearm area. The same procedure is repeated a month later.

Main outcome variables

Determination of Psoriasis Area and Severity Index

(PASI); evaluation of inflammatory factors of interleukin 10 and 17; Interferon-Gamma; tumor necrosis factor; Dermatology Life Quality Index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150601022512N3**

Registration date: **2019-03-09, 1397/12/18**

Registration timing: **prospective**

Last update: **2019-03-09, 1397/12/18**

Update count: **0**

Registration date

2019-03-09, 1397/12/18

Registrant information

Name

Masoud Maleki

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 3802 2510

Email address

malekim@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-11, 1397/12/20

Expected recruitment end date

2020-03-10, 1398/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of autologous adipose derived stem cells stromal vascular fraction (SVF) on the treatment of generalized plaque psoriasis

Public title

Evaluation of the effect of stromal vascular fraction (SVF) on the treatment of generalized plaque psoriasis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Body Mass Index value of 18 to 25 generalized plaque psoriasis based on Psoriasis Area and Severity Index (PASI) of more than 10 or based on more than 10% body involvement

Exclusion criteria:

coagulation disorder use of anticoagulation medicines heart, lung, kidney, liver diseases and malignancy contraindication for liposuction active infections including HIV, HCV, HBV, HTLV1 absence of mental health

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 5

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

Central Building of Mashhad University of Medical

Sciences (Ghorshi), Daneshgah 16, Daneshgah Street

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Approval date

2018-10-20, 1397/07/28

Ethics committee reference number

IR.MUMS.REC.1397.194

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

Generalized plaque psoriasis

ICD-10 code

L40.0

ICD-10 code description

Psoriasis vulgaris

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

Evaluation of interleukin serum level of 10

Timepoint

Before commencement of SVF injection and at 1, 3 and 6 months after the injection

Method of measurement

Venous blood sample

2**Description**

Measurement of severity of psoriasis

Timepoint

Before and after treatment

Method of measurement

Psoriasis Area and Severity Index (PASI) questionnaire

3**Description**

Quality-of-life Index of skin patients

Timepoint

Before and after treatment

Method of measurement

Dermatology Life Quality Index questionnaire

4**Description**

Evaluation of interleukin serum level of 17

Timepoint

Before commencement of SVF injection and at 1, 3 and 6 months after the injection

Method of measurement

Venous blood sample

5

Description

Evaluation of tumor necrosis factor alpha

Timepoint

Before commencement of SVF injection and at 1, 3 and 6 months after the injection

Method of measurement

Laboratory method

6

Description

Evaluation of Interferon-Gamma serum level

Timepoint

Before commencement of SVF injection and at 1, 3 and 6 months after the injection

Method of measurement

Laboratory method

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients are subjected to venous infusion of autologous adipose derived stem cells stromal vascular fraction (SVF) twice at intervals of one month. Each time, after an aspiration of 100 cc of adipose tissue and transfer to the the Academic Center for Education, Culture and Research, the achieved autologous SVF (0.5 to 20 million stem cells per 100 g) is injected intravenously into the patients' forearm area. The same procedure is repeated a month later. Then, patients will be examined during the first month after treatment, weekly for up to 1 month, and then monthly for up to 6 months.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Dermatology clinic, Imam Reza Hospital

Full name of responsible person

Masoud Maleki

Street address

Imam Reza Hospital, Imam Reza square, Ebn_e_sina Avenue

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Phone

+98 51 3802 2020

Email

malekim@mums.ac.ir

2

Recruitment center

Name of recruitment center

Dermatology clinic, Ghaem Hospital

Full name of responsible person

Faezeh Taghavi

Street address

Ghaem hospital, Ahmad Abad Ave

City

Mashhad

Province

Razavi Khorasan

Postal code

9176699199

Phone

+98 51 3801 2493

Email

taghavif941@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohsen Tafaghodi

Street address

Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Phone

+98 51 3841 2081

Email

ramresearch@mums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad University of Medical Sciences

Proportion provided by this source

100

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

Person responsible for general inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Faezeh Taghavi

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

Street address

Ghaem hospital, Ahmad Abad Ave

City

Mashhad

Province

Razavi Khorasan

Postal code

9176699199

Phone

+98 51 3801 2493

Email

taghavif941@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Masoud Maleki

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

Street address

Imam Reza Hospital, Imam Reza Square, Ebn_e_Sina Avenue

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Phone

+98 51 3802 2020

Email

malekim@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Faezeh Taghavi

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

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Ghaem hospital, Ahmad Abad Ave

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All data can be shared after patients are made unidentifiable.

When the data will become available and for how long

Data can be accessible 6 months after results are published.

To whom data/document is available

Data will be available for researchers in universities and other scientific institutes.

Under which criteria data/document could be used

Carrying out analysis on data is permitted.

From where data/document is obtainable

Data can be accessible through sending an email to the corresponding author.

What processes are involved for a request to access data/document

After sending a request email to the corresponding author, data will be sent in 1 month.

Comments