

# 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

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##### Province

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##### 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

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##### 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

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**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

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**Province**

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**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

**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

## 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**