

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

Safety and efficacy of injection of adipose tissue derived mesenchymal exosomes for skin lesions in patients with chronic plaque psoriasis

Protocol summary

Study aim

Determination of the Safety and efficacy of injection of adipose tissue-derived mesenchymal exosomes for skin lesions in patients with chronic plaque psoriasis

Design

parallel group, 12 patient, Phase I ,clinical trial

Settings and conduct

This study is performed on psoriasis patients. In the first phase of this study, 3 groups of 4 patients were selected. For these groups, 50, 100 and 200 micrograms per milliliter per square centimeter of skin lesion are injected, respectively. Also a lesion at the injection site with the same sensitivity and severity as the control. At a 3-month follow-up, the best dose is selected for best efficacy and minimal side effects.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 12 patients over 18 years, 6 months of history, PASI index 3 to10, low to moderate lesion severity (1 to 3), non-response to standard treatment, no lesion, or increase in the last 6 months. Exclusion Criteria: Other types of disease including pustular, erythrodermic, Use of immunosuppressive drugs in the past 2 weeks and topical drugs except for emollients in the past 2 weeks Severe underlying disease, increase in liver enzymes more than 3 times normal and creatinine more than 2, high and uncontrolled hypertension, pregnant or lactating women, Patients with diabetes, patients with hepatitis B, C or HIV, immunocompromised patients, malignant patients, debilitating disease, systemic infection or injection site

Intervention groups

Group 1 includes patients with psoriasis who receive a stem cell-derived exosome at a dose of 50 micrograms. Group 2 includes patients with psoriasis who receive a stem cell-derived exosome at a dose of 100 micrograms. Group 3 includes patients with psoriasis who receive a stem cell-derived exosome at a dose of 200 micrograms.

Main outcome variables

Side effects, severity of plaque, PASI measures,

inflammatory cytokines

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20080901001159N29**

Registration date: **2020-10-05, 1399/07/14**

Registration timing: **registered_while_recruiting**

Last update: **2020-10-05, 1399/07/14**

Update count: **0**

Registration date

2020-10-05, 1399/07/14

Registrant information

Name

Mohamad Ali Nilforoushzadeh

Name of organization / entity

Skin and Stem Cell Research Center, Tehran
University of Medical sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-05, 1399/05/15

Expected recruitment end date

2021-01-04, 1399/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Safety and efficacy of injection of adipose tissue derived mesenchymal exosomes for skin lesions in patients with chronic plaque psoriasis

Public title
Safety and efficacy of cell therapy in psoriasis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Chronic plaque psoriasis for at least 6 months plaque Mild to severity of moderate (grade 1-3) PASI 3-12 No response to standard treatments No incidence of new lesion or increase in size of previous lesions during past 3 months
Exclusion criteria:
Other types of psoriasis include pustular, erythrodermic, gutate, and drug induced Immunosuppressive drugs over the past 4 weeks or topical medications other than moisturizing lotions in the 2 past weeks Severe underlying disease (including liver, kidney and heart failure), increased liver enzymes more than 3 times normal and creatinine more than 2 high and uncontrolled blood pressure Pregnancy or lactation diabetes mellitus Hepatitis B, C or HIV Patients with immunodeficiency Patients with malignancy Disabling disease Systemic or injection site infection

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
1

Groups that have been masked
No information

Sample size
Target sample size: **12**

Randomization (investigator's opinion)
N/A

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 Tehran University Of Medical Sciences
Street address
Floor 13, Block A, Ministry of Health & Medical Education Headquarters, Between Zarafashan & South Falamak, Qods Town, Tehran, Iran.
City
Tehran
Province
Tehran
Postal code
1419943471
Approval date
2020-06-17, 1399/03/28
Ethics committee reference number
IR.TUMS.VCR.REC.1399.523

Health conditions studied

1

Description of health condition studied
Psoriasis
ICD-10 code
L40
ICD-10 code description
Psoriasis

Primary outcomes

1

Description
Pain
Timepoint
intervention start date up to 3 months
Method of measurement
Pain intensity scale

2

Description
Redness severity
Timepoint
intervention start date up to 3 months
Method of measurement
Physical examination

Secondary outcomes

1

Description
Lesion severity (grade 1-3)
Timepoint
Before intervention, every week up to 1 month, and every month up to 3 months
Method of measurement

evaluator assessment

Intervention groups

1

Description

Intervention First group: Single intra-dermal injection of 50 µg of exosomes derived from adipose tissue mesenchymal cells per cm² of plaque into 0.5 ml of normal saline and follow up to 3 months after injection. Also, in the same area of the lesion where the injection is performed, a lesion with the same sensitivity and severity is considered as a control. The Cells cultured in a cleanroom at the Skin and Stem Cell Research Center, Tehran University of Medical Sciences and, the exosomes are isolated using an ultracentrifuge

Category

Treatment - Drugs

2

Description

Intervention second group: Single intra-dermal injection of 100 µg of exosomes derived from adipose tissue mesenchymal cells per cm² of plaque into 0.5 ml of normal saline and follow up to 3 months after injection. Also, in the same area of the lesion where the injection is performed, a lesion with the same sensitivity and severity is considered as a control. The Cells cultured in a cleanroom at the Skin and Stem Cell Research Center, Tehran University of Medical Sciences and, the exosomes are isolated using an ultracentrifuge

Category

Treatment - Drugs

3

Description

Intervention Third group: Single intra-dermal injection of 200 µg of exosomes derived from adipose tissue mesenchymal cells per cm² of plaque into 0.5 ml of normal saline and follow up to 3 months after injection. Also, in the same area of the lesion where the injection is performed, a lesion with the same sensitivity and severity is considered as a control. The Cells cultured in a cleanroom at the Skin and Stem Cell Research Center, Tehran University of Medical Sciences and, the exosomes are isolated using an ultracentrifuge

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Skin and Stem Cell Research Center, Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Nilforoushzadeh

Street address

No 4. Maryam Alley. South Kamranyeh Street, Skin and Stem Cell Research Center , Tehran University of Medical Sciences, Tehran, Iran.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Skin and Stem cell Research Center of Tehran University of Medical Sciences

Full name of responsible person

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<http://skinstemcell.ir/>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Skin and Stem cell Research Center of Tehran 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

Skin and Stem Cell Research Center, Tehran
University of Medical sciences

Full name of responsible person

Mohamad Ali Mohseni Meybodi

Position

Researcher

Latest degree

Master

Other areas of specialty/work

Cellular and Molecular Biology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Skin and Stem Cell Research Center, Tehran
University of Medical Sciences, Tehran, Iran

Full name of responsible person

Mohammad Ali Nilforoushzadeh

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

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Person responsible for updating data

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University of Medical sciences

Full name of responsible person

Mona Mahmoudbeyk

Position

Research manager

Latest degree

Ph.D.

Other areas of specialty/work

Others

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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