

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

Safety and efficacy of transplantation of adipose derived stem cells for skin lesions in patients with plaque psoriasis- phase I clinical trial

Protocol summary

Study aim

Determining the Effectiveness and Investigating the Side Effects of Allogeneic transplantation of Adipose-derived Stem Cells on Skin Lesions of Patients with Psoriasis Plaque

Design

Two arms, parallel group, randomized, double blind, Phase I

Settings and conduct

This study is done on psoriasis patients referred to the Royan skin clinic. In the first phase, 2 groups of 3 patients are selected to receive 1 and 3 million ASCs per cm² of lesion, respectively. After 6 months follow-up, the best dose is chosen based on efficacy and safety outcomes.

Participants/Inclusion and exclusion criteria

Inclusion: patients older than 18 years of age, patients with chronic psoriasis plaque for at least 6 months, the Psoriasis Area Severity Index (PASI) index less than 12, plaque severity of moderate to severe (Grade 3 to 5), not response to standard treatments, absence of a new lesion, or an increase in the size of previous lesions in the last 6 months are included in the study. Exclusion: patients with other types of psoriasis including pustular, erythrodermic, guttate and drug induced, immunosuppressive drugs given in 4 weeks, and topical medications other than moisturizing lotions in the past 2 weeks, severe underlying disease (liver, kidney, and cardiac failure), Increased liver enzymes more than 3 times normal and creatinine more than 2, high and uncontrolled hypertension, pregnant or lactating, diabetes mellitus, patients with hepatitis B, C or HIV, immunocompromised patients, Malignancy, debilitating disease, and systemic infection or injection site are excluded.

Intervention groups

Allogeneic adipose-derived stromal cells in normal saline group

Main outcome variables

Side effects, severity of plaque psoriasis, PASI measures, inflammatory cytokines

General information

Reason for update

protocol amendment

Acronym

IRCT registration information

IRCT registration number: **IRCT20080728001031N24**

Registration date: **2018-05-30, 1397/03/09**

Registration timing: **registered_while_recruiting**

Last update: **2023-01-28, 1401/11/08**

Update count: **1**

Registration date

2018-05-30, 1397/03/09

Registrant information

Name

Nasser Aghdami

Name of organization / entity

Royan Institute

Country

Iran (Islamic Republic of)

Phone

+98 21 2356 2000

Email address

nasser.aghdami@royaninstitute.org

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-04-04, 1396/01/15

Expected recruitment end date

2021-04-04, 1400/01/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Safety and efficacy of transplantation of adipose derived stem cells for skin lesions in patients with plaque psoriasis- phase I clinical trial

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 severity of moderate to severe (grade 3-5) Psoriasis Area Severity Index (PASI) less than 12 No response to standard treatments No incidence of new lesion or increase in size of previous lesions during past 6 months

Exclusion criteria:

Other types of psoriasis include pustular, erythrodermic, gotate, 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

Gender

Both

Phase

1

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **5**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: Simple Randomization unit: Individual stratified randomization is not included Randomization Tool: Random number box Allocation concealment: The cell products with different doses are delivered to the physician with code numbers. Then the dressings will be placed on the patient's lesion based on randomization number box.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, patients, researchers, health care persons including its physician and nurse, and the outcome evaluator are blinded until the end of study. For this

purpose, the patient's lesions are divided into an intervention and control group based on the randomization table and the cell sample or placebo is sent to the physician with a code and the physician performs the injections according to the product label.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Royan infertility institute

Street address

Royan institute, Eastern Hafez St, Northern Banihashem St, 45 m Resalat highway

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Tehran

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Postal code

1665664511

Approval date

2015-04-15, 1394/01/26

Ethics committee reference number

1394.1.IR.ACECR.ROYAN.REC

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 6 months

Method of measurement

Pain intensity scale

2**Description**

Redness severity

Timepoint

intervention start date up to 6 months

Method of measurement

Physical examination

Secondary outcomes**1****Description**

Lesion severity (grade 0-5)

Timepoint

Before intervention, every week up to 1 month, and every month up to 6 months

Method of measurement

evaluator assessment

Intervention groups**1****Description**

Intervention group 1: Single intra-dermal injection of 1 million adipose-derived stromal cells per cm² of plaque (based on the results of Phase I study) into 0.5 ml of normal saline per cm² of plaque and follow up to 6 months after injection. The cells are provided by Cell Tech Pharmed company.

Category

Treatment - Drugs

2**Description**

Intervention group 2: Single intra-dermal injection of 3 million adipose-derived stromal cells per cm² of plaque (based on the results of Phase I study) into 0.5 ml of normal saline per cm² of plaque and follow up to 6 months after injection. The cells are provided by Cell Tech Pharmed company.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Royan Cell Therapy Center

Full name of responsible person

Nasser Aghdami

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Iranian academic center for education culture and research

Full name of responsible person

Abdolhossein Shahverdi

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Iranian academic center for education culture and research

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**

Iranian academic center for education culture and research

Full name of responsible person

Amir Bajouri

Position

Research physician

Latest degree

Medical doctor

Other areas of specialty/work

Medical Biotechnology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Iranian academic center for education culture and
research

Full name of responsible person

Nasser Aghdami

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Immunology

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Person responsible for updating data

Contact

Name of organization / entity

Iranian academic center for education culture and
research

Full name of responsible person

Hoda Madani

Position

Researcher/M.D

Latest degree

Medical doctor

Other areas of specialty/work

Medical Biotechnology

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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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data will be shared after unidentifiable of the patients

When the data will become available and for how long

6 months after paper publication

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

In term of analysis the data related to study outcomes

From where data/document is obtainable

amir.bajouri@royaninstitute.org

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

The request will be assessed by research committee of
Royan Institute which will be taken around 2 months

Comments