Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 recieve 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, gotate 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

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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 psorisis
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
City
Tehran
Province
Tehran
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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Eastern Hafez St,Northern Banihashem St, 45 m Resalat highway
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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
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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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Web page address

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 around2 months

Comments