

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Evaluation of the efficacy and safety of autologous cell transplantation without melanocyte-keratinocyte culture in suspension and gel form in the treatment of patients with persistent vitiligo: Phase one clinical trial

Protocol summary

Study aim

Evaluation of the efficacy and safety of autologous cell transplantation without melanocyte-keratinocyte culture in suspension and gel form in the treatment of patients with persistent vitiligo: Phase one clinical trial

Design

Phase 1, sample size of 10 people, with an intervention group and a control group, not blinded

Settings and conduct

This project is carried out in the Skin and Stem Cell Research Center of Tehran University of Medical Sciences, and with the patient's information about how to conduct the study, in order to evaluate the effectiveness of the treatment method and the side effects of transferring the melanocyte cell suspension and the gel containing the cells along with the dermabrasion method as an evaluation. It is done before and after. First, a small area of the patient's buttocks is used as a donor area. After the melanocyte cell suspension is prepared in the laboratory, the depigmented area is numbed and the epidermal area is removed. The suspension is completely poured on the exfoliated surface and then it is fixed in the lesion with a suitable dressing. In another patch, gel containing cells is placed. The dressing is removed in the first week after the operation. Biometry of patients is performed before intervention, 1, 3 and 6 months after transplantation.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Having no treatment within past 6 months, Exclusion criteria: Vitiligo patients with active or progressive disease within last 12 months.

Intervention groups

Intervention group: A diseased patch of patient dermabrade and a gel containing cells is placed on the area and bandaged. Control group: A patch of patient dermabrade and the cell suspension is sprayed on the area and bandaged.

Main outcome variables

Melanin Index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200127046282N22**

Registration date: **2023-02-05, 1401/11/16**

Registration timing: **prospective**

Last update: **2023-02-05, 1401/11/16**

Update count: **0**

Registration date

2023-02-05, 1401/11/16

Registrant information

Name

Sona Zare

Name of organization / entity

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

Country

Iran (Islamic Republic of)

Phone

+98 21 2665 7438

Email address

sonazarebio@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-20, 1401/12/01

Expected recruitment end date

2024-02-20, 1402/12/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the efficacy and safety of autologous cell transplantation without melanocyte-keratinocyte culture in suspension and gel form in the treatment of patients with persistent vitiligo: Phase one clinical trial

Public title
Evaluation of autologous cell transplantation without melanocyte-keratinocyte culture in suspension and gel form in the treatment of patients with persistent vitiligo

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Having no treatment within past 6 months No pregnancy or breast-feeding Have a diagnosis of vitiligo with depigmented patch more than 5 cm despite receiving at least 3 months active treatment No infection at recipient site No history of keloid and or koebner phenomenon No history of active hepatitis the B, C, or AIDS No active uncontrolled chronic systemic disease
Exclusion criteria:
Vitiligo patients with active or progressive disease within last 12 months.

Age
From **18 years** old to **50 years** old

Gender
Both

Phase
1

Groups that have been masked
No information

Sample size
Target sample size: **10**

Randomization (investigator's opinion)
Not randomized

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
Tehran University of Medical Sciences, Keshavarz blvd.

City
Tehran

Province
Tehran

Postal code
1417653761

Approval date
2022-05-09, 1401/02/19

Ethics committee reference number
IR.TUMS.MEDICINE.REC.1401.119

Health conditions studied

1

Description of health condition studied

Vitiligo

ICD-10 code

L80

ICD-10 code description

disorders of pigmentation

Primary outcomes

1

Description

repigmentation rate

Timepoint

Before, 1, 3 and 6 months after treatment

Method of measurement

The amount of melanin in the treated areas compared to before treatment using a maxameter device

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: A diseased patch of patient dermabrade and a gel containing cells is placed on the area and bandaged.

Category

Treatment - Other

2

Description

Control group: A patch of patient dermabrade and the cell suspension is sprayed on the area and bandaged.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

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

Full name of responsible person

Mohammad Ali Nilforoushzadeh

Street address

No 4, Maryam Alley, South Kamraniyeh Street

City

Tehran

Province

Tehran

Postal code

1937957511

Phone

+98 21 2665 7438

Email

Nilforoosh@sina.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Akbar Fotouhi

Street address

Tehran University of Medical Sciences, Keshavarz
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tums_edu@tums.ac.ir

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

Yes

Title of funding source

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

Sona Zare

Position

Researcher

Latest degree

Ph.D.

Other areas of specialty/work

Cellular and Molecular Biology

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No 4, Maryam Alley, South Kamraniyeh Street

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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

Full name of responsible person

Mohammad Ali Nilforoushzadeh

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Dermatology

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Person responsible for updating data

Contact

Name of organization / entity

Skin and Stem Cell Research Center, Tehran

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Researcher
Latest degree
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Other areas of specialty/work
Cellular and Molecular Biology
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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

Not applicable

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

Not applicable

Data Dictionary

Not applicable