

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Optimization of autologous melanocyte and keratinocyte cells suspension transplantation for vitiligo treatment

Protocol summary

Study aim

Optimization of using autologous cell suspension transplantation for the treatment of vitiligo

Design

This study is in phase 2 with a sample size of 15 people and has only one intervention group (without control group) and is not blind and without randomization.

Settings and conduct

This study is done at the skin and stem cell research center of Tehran university of medical sciences and by informing the patient about how to conduct the study, It is performed for the effectiveness of the treatment method and side effects of melanocyte cell suspension transfer along appropriate method. First, a small area of the patient's buttocks is used as a donor area. After preparing the melanocyte cell suspension in the laboratory, the pigment-free area is anesthetized and the epidermis area is removed. The suspension is poured completely on the peeled surface and then fixed at the lesion site with a suitable dressing. The dressing is removed in the first week after the operation. Patients' biometrics are performed before the intervention, 1, 3 and 6 months after transplantation.

Participants/Inclusion and 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 active uncontrolled chronic systemic disease. Exclusion criteria: Vitiligo patients with active or progressive disease within last 1 year.

Intervention groups

Intervention group: The epidermis layer of pigment-free area is first removed and then the processed cell suspension is transferred to the desired area and covered with a suitable dressing.

Main outcome variables

Melanin Index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200127046282N2**

Registration date: **2021-05-28, 1400/03/07**

Registration timing: **prospective**

Last update: **2021-05-28, 1400/03/07**

Update count: **0**

Registration date

2021-05-28, 1400/03/07

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

2021-06-10, 1400/03/20

Expected recruitment end date

2021-08-11, 1400/05/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Optimization of autologous melanocyte and keratinocyte cells suspension transplantation for vitiligo treatment

Public title

Optimization of transplantation of cell suspension in the treatment of 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 pigmented 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

2

Groups that have been masked

No information

Sample size

Target sample size: **15**

Randomization (investigator's opinion)

Not randomized

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

کمیته اخلاق در پژوهش دانشگاه علوم پزشکی تهران

Street address

Tehran University of Medical Sciences, Keshavarz blvd.

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Province

Tehran

Postal code

1417653761

Approval date

2021-04-07, 1400/01/18

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1400.034

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: The pigment-free area is first removed and then the processed cell suspension is transferred to the desired area and covered with a suitable dressing.

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

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No 4, Maryam Alley, South Kamraniyeh Street, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

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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
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
Tehran University of Medical Sciences
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Sona Zare
Position
Researcher
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Dermatology

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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