

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

Transplantation of autologous melanocyte and keratinocyte cells suspension with micro needling method for treatment of vitiligo

Protocol summary

Study aim

Determination of the efficacy of using autologous cell suspension transplantation along with microneedling method for the treatment of vitiligo

Design

The above study is in phase 2 with a sample size of 10 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 with micronidél supplementation 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 by microneedling. 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 12 months.

Intervention groups

Intervention group: The pigment-free area is first microneedled 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: **IRCT20080901001159N30**

Registration date: **2020-10-23, 1399/08/02**

Registration timing: **registered_while_recruiting**

Last update: **2020-10-23, 1399/08/02**

Update count: **0**

Registration date

2020-10-23, 1399/08/02

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)

Phone

+98 21 2220 5158

Email address

sdIrc@mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-20, 1399/02/01

Expected recruitment end date

2020-12-21, 1399/10/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Transplantation of autologous melanocyte and keratinocyte cells suspension with micro needling method for treatment of vitiligo

Public title
Transplantation of cell suspension with microneedling 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 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

Gender
Female

Phase
2

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
Single

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

2016-01-05, 1394/10/15

Ethics committee reference number

IR.TUMS.REC.1394.1558

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 microneedled 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

Clinics 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,
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Nilforoosh@sina.tums.ac.ir

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

Tehran University of Medical Sciences

Full name of responsible person

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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**

Skin and Stem Cell Research Center of Tehran

University of Medical Sciences

Full name of responsible person

Sona Zare

Position

Researcher

Latest degree

Ph.D.

Other areas of specialty/work

Cellular biology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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

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**Contact****Name of organization / entity**

Skin and Stem cell Research Center of Tehran
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Full name of responsible person

Mona Mahmoudbeyk

Position

Researcher

Latest degree

Ph.D.

Other areas of specialty/work

Developmental 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