

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jul 2026

### Evaluation of the Effectiveness of Microneedling versus Microdermabrasion for Preparation of Lesion Site for Autologous Melanocyte and Keratinocyte Transplantation for Cell Therapy in Patients with Vitiligo Stable Lesion: A pilot study

#### Protocol summary

The recovery rate of lesions of vitiligo patients

#### Study aim

Determining the effectiveness of microneedling versus dermabrasion to prepare the site of two different lesions in one patient for autologous melanocyte and keratinocyte transplantation for cell therapy in patients with persistent vitiligo lesions: a pilot study

#### Design

The study is a clinical pilot study involving ten patients (male and female) between 18 and 50 years of age. This project will enroll patients whose disease has not progressed and whose disease stability is confirmed by the absence of new lesions during the last year from the patient-reported medical history.

#### Settings and conduct

This study is a pilot clinical study that is conducted in collaboration with the Skin Molecular Research Center and at the Burn Research Center of Shiraz University of Medical Sciences in Amir Al Mominin Hospital. Ten eligible male or female patients between the ages of 18 and 50 years participate in this study. Preparation for cell transplantation site by micro-needling or dermabrasion method is also performed on two different lesions in the same patient.

#### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with stable vitiligo whose disease stability on the basis of the absence of new lesions within the past one year has been reported by using the patient's past medical history. Exclusion criteria: Patients with more than 30% body surface involvement, pregnant women, patients with skin cancer and patients who receive other vitiligo treatments

#### Intervention groups

Preparation of two different lesions in one patient by microneedling and dermabrasion method for cell transplantation

#### Main outcome variables

#### General information

##### Reason for update

The title of the project was changed due to the destruction of the vitiligo lesion by the fractional CO2 laser and the microneedling method was used instead of the laser. In addition, lesion preparation by microneedling and dermabrasion is performed in two different lesions on the same patient.

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20110731007160N8**  
Registration date: **2020-08-16, 1399/05/26**  
Registration timing: **prospective**

Last update: **2023-01-21, 1401/11/01**

Update count: **1**

##### Registration date

2020-08-16, 1399/05/26

##### Registrant information

###### Name

Nasrin Hamidizadeh

###### Name of organization / entity

Molecular Dermatology Research Center, Shiraz University of Medical Sciences, Shiraz, Iran

###### Country

Iran (Islamic Republic of)

###### Phone

+98 71 3212 5592

###### Email address

hamidizade@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

**Expected recruitment start date**

2021-01-19, 1399/10/30

**Expected recruitment end date**

2021-01-26, 1399/11/07

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Evaluation of the Effectiveness of Microneedling versus Microdermabrasion for Preparation of Lesion Site for Autologous Melanocyte and Keratinocyte Transplantation for Cell Therapy in Patients with Vitiligo Stable Lesion: A pilot study

**Public title**

Evaluation of the Effectiveness of Microneedling versus Microdermabrasion for Preparation of Lesion Site for Autologous Melanocyte and Keratinocyte Transplantation in Patients with Vitiligo Stable Lesion

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Patients who have stable vitiligo Patients whose disease has not progressed and whose disease stability is confirmed by the absence of new lesions during the last year from the patient-reported medical history.

**Exclusion criteria:**

Patients with more than 30% body surface involvement, and patients who receive other treatments for vitiligo, are not included in the study. pregnant women patients with skin cancer and other vitiligo treatments

**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**

Single

**Other design features****Secondary Ids**

empty

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

Ethics committee of Shiraz University of Medical Sciences

**Street address**

Molecular Dermatology Research Center Shahid Faghihi hospital, Zand Avenue, Shiraz-Iran

**City**

shiraz

**Province**

Fars

**Postal code**

7134844119

**Approval date**

2020-04-08, 1399/01/20

**Ethics committee reference number**

IR.SUMS.REC.1399.127

**Health conditions studied****1****Description of health condition studied**

Vitiligo

**ICD-10 code**

L80

**ICD-10 code description**

Vitiligo

**Primary outcomes****1****Description**

Melanin pigment production rate in skin

**Timepoint**

After 3 to 6 weeks of treatment

**Method of measurement**

Vitiligo Area Scoring Index (VASI)

**Secondary outcomes**

empty

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

A piece of pigmented skin is disinfected with a chlorhexidine solution and then anesthetized with lidocaine, and then an area of 2 to 4 cm of skin is removed and the wound sutured. Then the melanocyte and keratinocyte cells are separated from the epidermis. Then two different vitiligo lesions of the same patient are prepared by micro-needling and dermabrasion, respectively, and the prepared cell suspension is spread over these two areas, these lesions are then covered

with amniotic membranes.

**Category**

Treatment - Other

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Molecular Dermatology Research Center and Burn and Wound Healing Research Center of Shiraz Universit

**Full name of responsible person**

Dr.Nasrin Hamidizadeh

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**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Dr. Mahtab Memarpour

**Street address**

Vice-Chancellor for Research, Shiraz University of Medical Sciences, Zand Blvd

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**Province**

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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**

Shiraz 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**

Shiraz University of Medical Sciences

**Full name of responsible person**

Dr.Nasrin Hamidizadeh

**Position**

Manager of Research Center

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Immunology

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Shiraz University of Medical Sciences

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**Person responsible for updating data****Contact****Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Sara Ranjbar

**Position**

Research Expert

**Latest degree**

Master

**Other areas of specialty/work**

Others

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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**

Demographic characteristics of the results of cell therapy in vitiligo patients

**When the data will become available and for how long**

Immediately after the publication of the article

**To whom data/document is available**

Researchers

**Under which criteria data/document could be used**

Send researchers' requests via email and make a commitment to applicants to protect the data

**From where data/document is obtainable**

Sending researchers' requests via e-mail to the e-mail address of the executor and in charge of the project, Dr. Nasrin Hamidizadeh. n.hamidizadeh.mdrc@gmail.com

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

The applicant researcher should send his request to the email address of the executor of the project, Dr. Nasrin Hamidizadeh (n.hamidizadeh.mdrc@gmail.com). Within one week after evaluation, the data will be sent to the applicant via email, along with making a commitment.

**Comments**