Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

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

The recovery rate of lesions of vitiligo patients

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
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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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Molecular Dermatology Research Center Shahid Faghihi hospital, Zand Avenue

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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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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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Position

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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