

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 2026

### Comparison of therapeutic effects of 3 methods of microneedling with TCA 50%, microneedling and peeling TCA 50% each alone in acral vitiligo

#### Protocol summary

##### Study aim

Comparison of the effects of three methods of microneedling, TCA 50% and both together in improving acral vitiligo patients

##### Design

21 patients with vitiligo will be selected according to the inclusion criteria. Three similar lesions in terms of size, location and hair density are selected from the body in "each patient" and we treat one with TCA 50% peeling only, one with microneedling only, and the other with a combination of these two cases,, from each patient.

Three lesions should be selected and each lesion is counted as one group.

##### Settings and conduct

Patients referred to the dermatology clinic of Al-Zahra and Sediqah Tahereh hospitals. Before starting the treatment, patients fill out the patient information form and standard photography is done on each patient. In each patient, three lesions are selected and after the completion of the treatment and 3 months after the treatment, the level of satisfaction of the patients, possible complications and also the rate of healing of the lesions are done by 2 dermatologists.

##### Participants/Inclusion and exclusion criteria

Vitiligo patients who have not responded to other treatments will be included in the study. Cases that not to be included in the study include: 1. Age less than 11 years and more than 60 years 2. Pregnancy and breastfeeding 3. Presence of active vitiligo for 2 years 4. Absence of end limb lesions 5. Receiving treatment in the last 3 months 6. Allergy to the studied drugs 7. Not having at least three depigmented patches at the end of the body 8. Not having written consent to participate in the study

##### Intervention groups

In each patient, three lesions will be selected and each area will undergo a treatment method. The first method is microneedling, the second method is TCA 50% peeling, and the third method is both together

#### Main outcome variables

Patient satisfaction score - lesion recovery score

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20240204060900N1**

Registration date: **2024-02-07, 1402/11/18**

Registration timing: **retrospective**

Last update: **2024-02-07, 1402/11/18**

Update count: **0**

##### Registration date

2024-02-07, 1402/11/18

##### Registrant information

##### Name

Ali Ghadirian

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3131 5042

##### Email address

alighadirian@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-07-23, 1402/05/01

##### Expected recruitment end date

2025-01-19, 1403/10/30

##### Actual recruitment start date

2023-07-23, 1402/05/01

##### Actual recruitment end date

2024-01-20, 1402/10/30

## Trial completion date

2024-02-04, 1402/11/15

## Scientific title

Comparison of therapeutic effects of 3 methods of microneedling with TCA 50%, microneedling and peeling TCA 50% each alone in acral vitiligo

## Public title

Investigating the therapeutic effects of microneedling, TCA 50% and the combination of both in limb vitiligo

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Absence of active vitiligo for 2 years Not receiving treatment in the last 3 months Lack of sensitivity to the studied drugs Having at least three depigmented patches at the end of the limb

### Exclusion criteria:

Pregnancy and breastfeeding A history of scar and keloid formation in the body Received treatment in the last three months Presence of active vitiligo in the last 2 years

## Age

From **11 years** old to **60 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

## Sample size

Target sample size: **21**

Actual sample size reached: **21**

## Randomization (investigator's opinion)

N/A

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

In this study, the participants do not know about the intervention method. Considering that three different treatment methods are performed on each patient's hand, the participant does not know what intervention has been performed in each part. After conducting the study and preparing the before and after photos, the photos are given to two dermatologists and without knowing the type of intervention, the outcome is evaluated.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Research Ethics Committees of School of Medicine - Isfahan University of Medical Sciences

##### Street address

اصفهان، خیابان کاوه، کوچه فارابی، پلاک 36، واحد 3

##### City

isfahan

##### Province

Isfahan

##### Postal code

8193934501

#### Approval date

2023-07-18, 1402/04/27

#### Ethics committee reference number

IR.MUI.MED.REC.1402.157

## Health conditions studied

### 1

#### Description of health condition studied

acral vitiligo

#### ICD-10 code

L80

#### ICD-10 code description

Vitiligo

## Primary outcomes

### 1

#### Description

Lesion recovery score based on size

#### Timepoint

The recovery rate of the lesions after the end of the treatment and three months after the end of the treatment

#### Method of measurement

Observation of photos before and after treatment by 2 dermatologists and grading based on the degree of recovery

## Secondary outcomes

### 1

#### Description

Patient satisfaction score

#### Timepoint

Patient satisfaction score after treatment and 3 months after completion of treatment

#### Method of measurement

Visual Analog Scale Questionnaire

## Intervention groups

### 1

#### Description

Microneedling with Dr. Pen brand microneedling with a length of 1.5 mm every three weeks in one area, 4 steps

#### Category

Treatment - Devices

### 2

#### Description

Intervention group: TCA (Trichloroacetic acid) peeling 50% in one area, every three weeks, for 4 stages

#### Category

Treatment - Drugs

### 3

#### Description

Intervention group: First, microneedling with Dr. Pen brand microneedling with a length of 1.5 mm and then TCA (Trichloroacetic acid) 50% peeling in one area, every three weeks, for 4 steps.

#### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Dermatology Clinic of Al-Zahra Hospital

##### Full name of responsible person

Ali ghadirian

##### Street address

Dermatology clinic., Alzahra hospital., Sofe Blvd., Shahid Keshvari Niloufar Highway., Isfahan

##### City

isfahan

##### Province

Isfahan

##### Postal code

7573181746

##### Phone

+98 31 3822 0000

##### Email

alzahra@mui.ac.ir

### 2

#### Recruitment center

##### Name of recruitment center

Sedighe Tahere Clinic

##### Full name of responsible person

Ali ghadirian

##### Street address

After Shahidan Cross., Khorram St., Isfahan

##### City

isfahan

##### Province

Isfahan

##### Postal code

8174673461

##### Phone

+98 31 3339 0101

##### Email

alzahra@mui.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Esfahan University of Medical Sciences

##### Full name of responsible person

Isfahan University of Medical Sciences Research Assistant

##### Street address

Alzahra hospital., Sofe Blvd., Shahid Keshvari Niloufar Highway., Isfahan

##### City

isfahan

##### Province

Isfahan

##### Postal code

7573181746

##### Phone

+98 31 3822 0000

##### Email

alzahra@mui.ac.ir

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

##### Full name of responsible person

Ali Ghadirian

##### Position

resident

##### Latest degree

Medical doctor

**Other areas of specialty/work**

Dermatology

**Street address**

Dermatology clinic., Alzahra hospital., Sofe Blvd.,  
Shahid Keshvari Niloufar Highway., Isfahan

**City**

Isfahan

**Province**

Isfahan

**Postal code**

7573181746

**Phone**

+98 31 3822 0000

**Email**

alighadirian@yahoo.com

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

Esfahan University of Medical Sciences

**Full name of responsible person**

Ali Ghadirian

**Position**

resident

**Latest degree**

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

Esfahan University of Medical Sciences

**Full name of responsible person**

Ali Ghadirian

**Position**

resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

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**Postal code**

7573181746

**Phone**

+98 31 3822 0000

**Email**

alighadirian@yahoo.com

**Web page address****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**

Undecided - It is not yet known if there will be a plan to make this available

**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**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available