Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 tiligo 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
Isfehan
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
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alzahra@mui.ac.ir

2

Recruitment center
Name of recruitment center
Sedighe Tahere Clinic
Full name of responsible person
Ali ghadirian
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After Shahidan Cross., Khorram St., Isfahan
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isfahan
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8174673461
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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
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Alzahra hospital., Sofe Blvd., Shahid Keshvari Niloufar Highway., Isfahan
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7573181746
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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
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Person responsible for updating data

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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
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