Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jun 2026

Comparison the Effect of Three Different Type of Treatment in Patients Being Treated for Vitiligo Lesions: 1. Microneedling, 2. Microneedling with Topical Fluocinolone and 3. Microneedling with 5-FU

Protocol summary

Study aim

Comparison the Effect of Three Different Type of Treatment in Patients Being Treated for Vitiligo Lesions: 1. Microneedling, 2. Microneedling with Topical Fluocinolone and 3. Microneedling with 5-FU

Design

A prospective, controlled, parallel-group, simple randomization clinical trial of 20 patients with 60 vitiligo lesions

Settings and conduct

This study will be carried out in Imam Khomeini Hospital of Ahvaz affiliated to the Faculty of Medicine of Ahvaz University of Medical Sciences. Demographic characteristics of patients including age, sex, family history of vitiligo, description of previous treatments, duration of disease and lesion location are recorded at the beginning. After that, the studied treatments are performed on the patient every week and the results of the previous procedures are also recorded. This work will continue for three months. After completing the study, the patients will be monitored for six months and the amount of changes in the lesion will be recorded.

Participants/Inclusion and exclusion criteria

Patients with stable vitiligo and no new lesions in the previous six months Except: pregnant Lactation Age under ten years Facial lesions, genitalia and wrinkled areas Active Kubner phenomenon Having coagulation diseases Patients with active infection Patient with high risk of keloid and previous history of keloid Presence of sensitivity to the study drugs

Intervention groups

Three patches are selected for each patient. A patch for combination of microneedling and fluocinolone is applied as a control, second patch for combination of microneedling and local fluorouracil, and third patch for microneedling alone

Main outcome variables

G-Score; Age; Gender; Skin type; Family history; Previous treatments; duration of lesions; Repigmentation start date

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220806055626N1**
Registration date: **2023-01-08, 1401/10/18**
Registration timing: **registered_while_recruiting**

Last update: **2023-01-08, 1401/10/18**
Update count: **0**

Registration date

2023-01-08, 1401/10/18

Registrant information

Name

Nasrin Kheirkhah

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3311 3938

Email address

kheirkhah.n@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-21, 1401/09/30

Expected recruitment end date

2023-04-19, 1402/01/30

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison the Effect of Three Different Type of Treatment in Patients Being Treated for Vitiligo Lesions: 1. Microneedling, 2. Microneedling with Topical Fluocinolone and 3. Microneedling with 5-FU

Public title
Comparison the Effect of Three Different Type of Treatment in Patients Being Treated for Vitiligo Lesions: 1. Microneedling, 2. Microneedling with Topical Fluocinolone and 3. Microneedling with 5-FU
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All patients with stable vitiligo without new lesions in the previous six months who have read and signed the consent form
Exclusion criteria:
Pregnant Women Lactating Mothers Facial lesions, genitalia and wrinkled areas Active koebner phenomenon Having coagulation diseases Patients with active infection Patient with high risk of keloid and previous history of keloid Presence of sensitivity to the study drugs
Age
From **10 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **20**
More than 1 sample in each individual
Number of samples in each individual: **60**
Vitiligo lesions in homogeneous areas of the patient's skin
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Golestan Hospital
Street address
Golestan Hospital, Golestan Ave., Ahvaz
City
Ahvaz
Province
Khouzestan
Postal code
6135733118
Approval date
2022-07-17, 1401/04/26
Ethics committee reference number
IR.AJUMS.HGOLESTAN.REC.1401.051

Health conditions studied

1

Description of health condition studied
Vitiligo
ICD-10 code
L80
ICD-10 code description
Vitiligo

Primary outcomes

1

Description
Vitiligo lesions repigmentation
Timepoint
At the beginning of the study; After starting the study every week for three months; Three and six months after completing the study
Method of measurement
The amount of change in the area of the lesion after treatment by examining the photos in color analysis software

Secondary outcomes

1

Description
G-score
Timepoint
After the beginning of repigmentation every week, every month after the end of the study for up to six months
Method of measurement
Color analysis software

2

Description

Repigmentation start time

Timepoint

After starting to study, every week

Method of measurement

Observing the color change through photo analysis

Intervention groups

1

Description

Control group: The combination of microneedling and fluocinolone; In this group, dermapen cartridge 36 (Dr.Pen brand) microneedling with a thickness of 1.5 mm is performed once a week until Pinpoint Bleeding occurs, and after that the patient uses fluocinolone 0.025% cream twice a day.

Category

Treatment - Drugs

2

Description

Intervention group: Microneedling; In this group, microneedling is performed only once a week. Before performing the process of all three patches, the lesion site is numbed for 20 minutes after sterilizing with 70% alcohol using lidocaine cream.

Category

Treatment - Other

3

Description

Intervention group: Combination of microneedling and topical fluorouracil; In this group, microneedling is performed once a week, and immediately after microneedling, 5% FU cream is applied on the surface of the lesion as a thick layer, then the lesion is covered with a closed dressing for 24 hours. After opening the dressing, the desired area is washed and cleaned. Also, the patient uses 5-FU cream topically on the lesion once a day. The duration of treatment for each person is three months, during which the patient undergoes microneedling 12 times with 5-FU cream.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam-Khomeini Hospital

Full name of responsible person

Nasrin Kheirkhah

Street address

Azadegan Ave.

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6193673166

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Web page address

http://himam.ajums.ac.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mehrnoosh Zakerkish

Street address

Golestan Ave.

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1579461357

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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

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Nasrin Kheirkhah

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology
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Dermatology Dep, Emam Khomeini Hospital, Azadegan Ave.
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Nasrin Kheirkhah
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Dermatology
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Person responsible for updating data

Contact
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Position
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Other areas of specialty/work
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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