Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparing the treatment effects of microneedling, pimecrolimus and microneedling with pimecrolimus methods on the improvement of vitiligo patients

Protocol summary

Study aim

Comparison of the effect of micronideling, pimecrolimus ointment and a combination of both in the treatment of vitiligo patients

Design

15 patients with vitiligo will be selected by inclusion criteria. Three similar lesions in size, location, and hair density are selected from "each patient" from the trunk or limb, and we treat one with pimecrolimus alone, one with microneedling alone, and the other with a combination of the two, in fact, Three lesions should be selected of each patient and each lesion counted as one group.

Settings and conduct

Patients referred to the dermatology clinic of Al-Zahra Hospital and Sedigheh Tahereh were selected based on inclusion criteria. Fill in the patient information form and DLQI form before starting treatment, and standard photography is performed on each patient. Three lesions will be selected in each patient and each will be subjected to a single treatment group. To evaluate the impact of treatment, indicators of improvement, patient satisfaction, physician satisfaction, and side effects in all three groups at the time of presentation and twice weekly. About Standardized global photography, Photographs before and 9 months after treatment are reviewed by two dermatologists who are blind to the study.

Participants/Inclusion and exclusion criteria

Patients with vitiligo who have not responded to other treatments will be included in the study. Patients with the above conditions that have contraindications to Pimicrolimus or Microneedling or have received systemic treatment within one month prior to enrollment will not be included in the study.

Intervention groups

The first group will be treated with micronideling and the second group with pimecrolimus ointment and the third group combination of microneedling and pimecrolimus ointment

Main outcome variables

DLQI Score - Score of phototherapy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190521043664N1**
Registration date: **2020-03-15, 1398/12/25**
Registration timing: **registered_while_recruiting**

Last update: **2020-03-15, 1398/12/25**
Update count: **0**

Registration date

2020-03-15, 1398/12/25

Registrant information

Name

Zahra Talebzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3458 3702

Email address

zahratalebzadeh61@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-13, 1398/08/22

Expected recruitment end date

2020-08-12, 1399/05/22

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing the treatment effects of microneedling, pimecrolimus and microneedling with pimecrolimus methods on the improvement of vitiligo patients

Public title
Comparison of pimecrolimus and microneedling effects in the treatment of vitiligo
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Written consent to participate in the study Stability of the disease within the last year if the disease has not progressed in the last year Existence of lesions on the trunk and limb Patients who did not respond appropriately to phototherapy, topical and systemic therapy.
Exclusion criteria:
Pregnancy and lactation Active vitiligo lesion Sensitivity to pimecrolimus Administration of systemic and topical treatments for vitiligo one month before enrollment
Age
From **11 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **15**
More than 1 sample in each individual
Number of samples in each individual: **3**
Three different vitiligo lesions with almost identical dimensions in almost similar areas of the body
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 Isfahan University of Medical Sciences
Street address
Soffeh Blvd
City
Isfahan
Province
Isfehan
Postal code
8174675731
Approval date
2019-11-12, 1398/08/21
Ethics committee reference number
IR.MUI.MED.REC.1398.413

Health conditions studied

1

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

Primary outcomes

1

Description
Photographic Scoring for patients with vitiligo
Timepoint
Before and 9 months after the study
Method of measurement
Score to photography

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group2: application of pimecrolimus ointment on vitiligo lesion on two times a day for three months
Category
Treatment - Drugs

2

Description
Intervention group1: microneedling on patient's vitiligo lesion every two weeks for three months
Category

Treatment - Devices

3

Description
Intervention group3: application of pimecrolimus ointment on vitiligo lesion two times a day for three months and microneedling on patient's vitiligo lesion every two weeks for three months

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
al-zahra hospital

Full name of responsible person
zahra talebzadeh

Street address
Soffe Blvd

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8174675731

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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
Shaghayegh Haghjoo Javanmard

Street address
Hezarjarib Street

City
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8174673461

Phone
+98 31 3668 8138

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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
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
zahra talebzadeh

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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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
The primary outcome data will be shared
When the data will become available and for how long
Start the access period is 6 months after publishing the results
To whom data/document is available
Academic researchers
Under which criteria data/document could be used
The request can be made by e-mail to the corresponding author
From where data/document is obtainable
It can be done by e-mail to zahratalebzade61@gmail.com
What processes are involved for a request to access data/document
Once the applicant has provided details of their ongoing project within one month from the time of application data will be available.
Comments