

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 microneedling, 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 Pimecrolimus 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 microneedling 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

Isfahan

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

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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

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Hezarjarib Street

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Isfahan

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8174673461

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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

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

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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