

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

Comparison of the Efficacy of Microneedling plus topical 5-FU versus topical Tacrolimus in the Treatment of Vitiligo Patients

Protocol summary

Study aim

Investigation of the effect of Microneedling with topical Fluorouracil (5-FU) in treatment of Vitiligo

Design

This is a clinical trial study that has control group, with a parallel group, randomized without blinding. This study will be performed on 20 patients from March to September 2020.

Settings and conduct

This study will be conducted at Imam Khomeini Hospital related to Ahvaz University of Medical Sciences. In each patient, two patches are selected and after randomization, one patch receives topical Tacrolimus drug as a control and the other receives a combination of topical Microneedling and a Fluorouracil.

Participants/Inclusion and exclusion criteria

All patients with stable Vitiligo can enter the study. Excluding criterias are: under 10 years of age, pregnant and lactating women, facial lesions and intertriginous areas and genitalia, active infection, history of keloid, drug allergy, coagulopathy history and active Koebner phenomenon

Intervention groups

One group receives Microneedling with topical Fluorouracil and the control group receives topical Tacrolimus ointment.

Main outcome variables

Response rate to Vitiligo treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200506047320N1**

Registration date: **2020-06-30, 1399/04/10**

Registration timing: **registered_while_recruiting**

Last update: **2020-06-30, 1399/04/10**

Update count: **0**

Registration date

2020-06-30, 1399/04/10

Registrant information

Name

Mohammad Hatami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3636 4577

Email address

hatami.mo@mail.ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-20, 1399/01/01

Expected recruitment end date

2020-09-21, 1399/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Efficacy of Microneedling plus topical 5-FU versus topical Tacrolimus in the Treatment of Vitiligo Patients

Public title

Microneedling plus topical 5-FU in treatment of Vitiligo

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All patients with stable vitiligo

Exclusion criteria:

Pregnancy and lactation Age under 10 y Lesions on face, genitalia and intertriginous areas Active Koebner phenomenon Coagulopathy Active infection Previous history of keloid or high risk for keloid Drug hypersensitivity

Age

From **10 years** old

Gender

Both

Phase

3

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: **2**

One sample receives topical Tacrolimus and other receives Microneedling plus 5FU

Randomization (investigator's opinion)

Randomized

Randomization description

Double randomized blocks containing treatment A and B are used to randomize the allocation of treatments to patients. To do this, two types of blocks; AB (where treatment B for the right and treatment A for the left) and BA (where treatment A for the right and treatment B for the left) are considered. By throwing a dice, if the even number appears, the AB block and if the odd number appears, the BA block is used to assign therapies to the patients.

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 Ahvaz University of Medical Sciences

Street address

9/1 Alley, Shahamat Ave., Akbarabad Blvd., Shiraz town

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Ahvaz

Province

Khuzestan

Postal code

7196881117

Approval date

2020-03-14, 1398/12/24

Ethics committee reference number

IR.AJUMS.REC.1398.983

Health conditions studied

1

Description of health condition studied

Vitiligo

ICD-10 code

L80

ICD-10 code description

Vitiligo

Primary outcomes

1

Description

Repigmentation level in Vitiligo lesions

Timepoint

At beggining of study and then after treatmen starts every 2 weeks for 3 months

Method of measurement

Based on the percentage of repigmentation and classification as 0 to 25 percent, 25 to 50, 50 to 75 and above 75 percent.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: A group that receives a combination of Microneedling and topical Fluorouracil solution 50 mg/ml every two weeks for 3 months.

Category

Treatment - Drugs

2

Description

Control group: A group that uses topical Tacrolimus 0.1% twice daily for 3 months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dermatology Clinic of Imam Khomeini Hospital in Ahvaz

Full name of responsible person

Nader Pazyar

Street address

9/1 Alley, Shahamat Ave., Akbarabad Blvd., Shiraz town

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

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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

Mohammad Hatami

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

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Assistant Professor

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Specialist

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

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Full name of responsible person

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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

All data can be published and shared after the study performed.

When the data will become available and for how long

3 months after publishing the results

To whom data/document is available

All groups and individuals

Under which criteria data/document could be used

There are no specific conditions at this moment.

From where data/document is obtainable

By contact with this email address

Hatami.mo@mail.ajums.ac.ir

What processes are involved for a request to access data/document

After submitting the request, data will be provided to them within a month

Comments