

# 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

**City**

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

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

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Mohammad Hatami

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dermatology

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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****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Nader Pazyar

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dermatology

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

Ahvaz University of Medical Sciences

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**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

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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**