

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

comparison of the effectiveness of 5-FU and tacrolimus ointment in the treatment of vitiligo vulgaris

Protocol summary

Study aim

Comparison of the efficacy of 5-FU and tacrolimus ointment in the treatment of vitiligo vulgaris

Design

Clinical trial without randomization, without a control group, two parallel intervention groups, double-blind, phase 2 on 40 patients.

Settings and conduct

In this double-blind clinical trial, 40 patients referring to the skin clinic of Imam Khomeini Hospital (RA) and skin and hair clinics in Ilam city were selected and will be randomly divided into two intervention treatment groups between February 1401 and August 1402. For the first intervention group, the use of 0.1% tacrolimus topical ointment and for the second intervention group, the use of 5-fluorouracil (FU-5) ointment on body lesions will be prescribed twice a day.

Participants/Inclusion and exclusion criteria

The presence of at least two vitiligo lesions in the upper, lower and trunk limbs similar in size and color (if the patient had several depigmented lesions, among them two lesions that were similar in size and color were selected would be); Age above 12 years; Have the possibility to refer and follow up; Having consent based on participating in the study; Not using topical treatments in the last month; Fixed or progressive course of the disease in a person; At least 10% of the body surface is affected by this disease; No immune

Intervention groups

Group A patients are treated with tacrolimus ointment and group B patients are treated with 5-fluorouracil (FU-5) ointment.

Main outcome variables

Size of the Vitiligo lesion, percentage of pigmentation of the lesion.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230115057128N1**

Registration date: **2023-02-19, 1401/11/30**

Registration timing: **registered_while_recruiting**

Last update: **2023-02-19, 1401/11/30**

Update count: **0**

Registration date

2023-02-19, 1401/11/30

Registrant information

Name

Fatemeh Raoufi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 84 3224 0029

Email address

dr.raoufi.f@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-21, 1401/11/01

Expected recruitment end date

2023-07-23, 1402/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison of the effectiveness of 5-FU and tacrolimus ointment in the treatment of vitiligo vulgaris

Public title

comparison of the effectiveness of 5-FU and tacrolimus ointment in the treatment of vitiligo vulgaris

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

The presence of at least two vitiligo lesions in the upper, lower and trunk limbs similar in size and color (if the patient had several depigmented lesions, among them two lesions that were similar in size and color were selected would be) Age above 12 years have the possibility to refer and follow up Consent based on participating in the study Not using topical treatments in the last month The steady or progressive course of the disease in a person Occupancy of at least 10% of the body surface by this disease Not having an immune deficiency

Exclusion criteria:

Patients with skin lesions on the face Cases of segmental vitiligo pregnancy Inability to track treatment results

Age

From **12 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description

In the questionnaire, each patient's lesion will be marked with code 1 and 2, and the researcher will not know the type of drug used in each location until the time of analysis. The patient does not know the type of medicine by giving the medicine in special containers.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee**

Name of ethics committee

Ethics Committee of Ilam University of Medical Sciences

Street address

Research and Technology Blvd., Ilam University of Medical Sciences campus, Banganjab, Ilam

City

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Postal code

6939177143

Approval date

2023-01-09, 1401/10/19

Ethics committee reference number

IR.MEDILAM.REC.1401.187

Health conditions studied**1****Description of health condition studied**

vitiligo vulgaris

ICD-10 code

L80

ICD-10 code description

Vitiligo

Primary outcomes**1****Description**

Size of the lesion

Timepoint

Examining the lesions at the beginning of the study and the second, fourth and sixth months after the start of treatment

Method of measurement

VASI scoring system

2**Description**

Percentage of pigmentation

Timepoint

Examining the lesions at the beginning of the study and the second, fourth and sixth months after the start of treatment

Method of measurement

VASI scoring system

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group 1: For the first intervention group, the use of 0.1% tacrolimus topical ointment on body lesions

will be prescribed twice a day (in the morning after waking up and at night before going to bed).

Category

Treatment - Drugs

2

Description

Intervention group 2: For the second intervention group, the use of 5-fluorouracil (FU-5) ointment on body lesions twice a day (in the morning after waking up and at night before going to bed) will be prescribed.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Fariba Shadfar

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Imam Khomeini Hospital, Ayatollah Heydari Street, Ilam

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ilam University of Medical Sciences

Full name of responsible person

Abbas Maleki

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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

Ilam University of Medical Sciences

Proportion provided by this source

50

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

Ilam University of Medical Sciences

Full name of responsible person

Fatemeh Raoufi

Position

medical student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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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