Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Evaluation of the effect of tofacitinib ointment in comparison with placebo in the treatment of patients with vitiligo undergoing phototherapy

Protocol summary

Study aim

Determination of efficacy of Tofacitinib ointment in the treatment of vitiligo

Design

A clinical trial with a control group, with parallel groups, double-blinded, randomized, phase 3 on 46 patients. Random Allocation software is used for randomization.

Settings and conduct

This study is conducted on patients with vitiligo who are referred to skin clinics of Shiraz University of Medical Sciences. Patients' lesions are randomly divided into two groups, including intervention and control groups. The plan is implemented in a double-blind manner.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: 1. Age over 18 years. 2. Presence of depigmented lesions on the upper extremities, lower extremities, face, or trunk that are similar in size and color. 3. No use of any topical medications in the past month. 4. Stable or progressive course of the disease. 5. Involvement of at least 20% of the body surface area. Exclusion Criteria: 1. History of any skin cancer or immunodeficiency. 2. Unwillingness to participate in the study. 3. Inability to follow up or attend follow-up appointments.

Intervention groups

Patients on one side of the body receive tofacitinib ointment as the intervention group, which should be applied once daily for three months. Patients on the opposite side of the body receive a topical placebo as the control group, which is also applied once daily for three months.

Main outcome variables

VASI; VAS; Patient global assessment (PGA); physician global assessment(PGA); Side effect

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150825023753N27**
Registration date: **2025-04-20, 1404/01/31**
Registration timing: **prospective**

Last update: **2025-04-20, 1404/01/31**
Update count: **0**

Registration date

2025-04-20, 1404/01/31

Registrant information

Name

Mohammad Mahdi Parvizi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-05-21, 1404/02/31

Expected recruitment end date

2025-11-21, 1404/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluation of the effect of tofacitinib ointment in comparison with placebo in the treatment of patients with vitiligo undergoing phototherapy

Public title
Effect of tofacitinib in the treatment of patients with vitiligo

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age over ۱۸ years Presence of depigmented lesions in the upper, lower limbs, face or trunk that are similar in size and color Not using any topical drugs in the last one month Stable or progressive course of the disease Involvement of at least ۲۰% of the body surface Consent to participate in this study

Exclusion criteria:
Any history of skin cancer or immunodeficiency, Unwillingness to participate in the study The impossibility of follow-up and refer for follow-up

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **46**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, selected patients must have at least ۲ similar lesions of the same color and size; therefore, one of the lesions on one side of the body as an intervention and the lesion on the other side will be selected as a control. Intervention lesions will be treated by tofacitinib ointment and control lesions by placebo, which is completely identical in shape, color and consistency to the original drug. In the information form, the lesions on each side of the patient will be marked with code ۱ and ۲, and two ointments will be distributed under the code A and B. The researcher will not know about the type of drug until the time of data analysis. To randomize the patients, the code number one belongs to the right side and number two to the left side. These two numbers are placed separately in a closed envelope. The letters A and B are placed separately in two envelopes .Each patient randomly chooses an envelope of numbers and an envelope of letters. Based on that Which number and which letter he chooses, the right or left side will be treated with ointment containing code A or B.

Blinding (investigator's opinion)
Double blinded

Blinding description
Blinding will be done in such a way that the content of A and B ointments will be divided by the drug manufacturer, and only the drug manufacturer know about the content of the tubes .Collecting information before, ۴۵ days and ۹۰ days after the procedure will be done by the project executor and the patient and the project executor will not be aware of the type of ointments. In the data analysis stage, the project executor analysis the data with the name of the groups (so they will not be aware of the description of the operation). Therefore, this study is double-blind, and the contents of the two groups of ointments will not be known from the stage of the patient's entry into the study until the completion of the study, data collection and data analysis.

Placebo
Used

Assignment
Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Shiraz University Of Medical Science

Street address
Shiraz University of Medical Sciences, Zand blv., Shiraz, Fars, Iran

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Shiraz

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Postal code
7134846114

Approval date
2024-08-30, 1403/06/09

Ethics committee reference number
IR.SUMS.MED.REC.1403.367

Health conditions studied

1

Description of health condition studied
Vitiligo

ICD-10 code
L80

ICD-10 code description
Vitiligo

Primary outcomes

1

Description
Vitiligo

Timepoint
0,45,90 days later
Method of measurement
Physical exam

Secondary outcomes

1

Description
Vitiligo Area Scoring Index
Timepoint
0,45,90 days later
Method of measurement
The information form for the Vitiligo Area Scoring Index (VASI)

Intervention groups

1

Description
Intervention group: receiving daily tofacitinib ointment for three month.
Category
Treatment - Drugs

2

Description
Control group: receiving placebo daily for three month.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Faghihi hospital
Full name of responsible person
Mehdi Ghahartars
Street address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Maryam Hekmat
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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
Demographic data and the result of the clinical trial

When the data will become available and for how long
starting 6 months after publication

To whom data/document is available
The data will be accessible to researchers working at academic and scientific institutions as well as those employed in the industry.

Under which criteria data/document could be used
After the publication of the article based on the clinical trial, it will be possible to share the data. The recipients of the data can use the data by obtaining permission from the project managers. The managers of this project will allow the data to be used in secondary data analysis studies and systematic reviews.

From where data/document is obtainable
Data requesters can submit their request by sending an email to each of the administrators that their names and emails have been entered into this system.

What processes are involved for a request to access data/document
Data requesters can submit their request by sending an email to each of the administrators that their names and emails have been entered into this system.

Comments