

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Comparative efficacy of 0.1% Tacrolimus ointment versus 0.005% Calcipotriol ointment in perifollicular pigmentation in patients with hand and facial vitiligo

Protocol summary

Summary

The present study is a randomized double-blind clinical trial. The aim of this study is to compare the efficacy of 0.1% Tacrolimus ointment versus 0.005% Calcipotriol ointment in reducing perifollicular pigmentation in patients with hand and facial vitiligo. The study will be conducted in the dermatology clinic of the Sina hospital in Tabriz. Seventy patients with hand and facial vitiligo will be recruited. The patients should be older than 2 years old, willing to participate in the study and should not have any other diseases which can affect the response of the patient to the treatment. All patients will be assessed by a dermatologist at baseline of the study, then will be entered into either group A or B. Patients in group A and B will be administered 0.005% Calcipotriol and 0.1% Tacrolimus respectively. The patients will be blind to the type of ointment they use. The amount of ointment used by the participants will be similar for the two groups and it will be applied on the lesions once every night. The degree of perifollicular pigmentation is considered as the primary outcome in this trial. The patients will be followed monthly for one year and the assessment of the outcomes (perifollicular pigmentation, number and size of the lesions) will be performed by a dermatologist who is blind to the type of ointment used by the patient. Every month, a photograph will be taken from the patients using a 12.1 mega pixel Cannon camera with a lens zoom of 4*15. After final assessments of the participants and recording their data in the checklists, statistical analyses will be performed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201208144269N4**
Registration date: **2012-10-10, 1391/07/19**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2012-10-10, 1391/07/19

Registrant information

Name

Farideh Golfroushan

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 41 1541 2101

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor of Research, Tabriz University of Medical Sciences

Expected recruitment start date

2012-11-29, 1391/09/09

Expected recruitment end date

2014-06-29, 1393/04/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative efficacy of 0.1% Tacrolimus ointment versus 0.005% Calcipotriol ointment in perifollicular

pigmentation in patients with hand and facial vitiligo

Public title

Comparative efficacy of Tacrolimus ointment versus Calcipotriol ointment in vitiligo

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1) Being older than 2 years old; 2) Vitiligo patients in which less than 20% of the face and hands are affected; 3) Willing to participate in the study
Exclusion criteria: 1) History of herpes, dermatitis herpetiformis and any kind of active skin infections; 2) Patients with autoimmune hepatitis; 3) Patients with celiac disease; 4) Patients with immune system deficiency; 5) Pregnant or lactating women; 6) Patients with unknown systemic disorders; 7) Having simultaneous skin diseases other than vitiligo, malignancies or renal disorders

Age

From **2 years** old to **85 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

The patients will be randomized into group A or B, using table of random numbers and the software RAND list. The ointments will be provided in plastic containers. Code A or B will be used for the containers. The physician, who will assess the patients monthly, will be different than the one who will prescribe the ointments to the patients at the baseline of the trial. Thus, the study will be double blinded.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Golbad Ave., Daneshgah St. Tabriz, Iran

City

Tabriz

Postal code

Approval date

2012-06-11, 1391/03/22

Ethics committee reference number

5/4/2703

Health conditions studied

1

Description of health condition studied

Vitiligo

ICD-10 code

L80

ICD-10 code description

Vitiligo

Primary outcomes

1

Description

Perifollicular pigmentation

Timepoint

At baseline and monthly for one year

Method of measurement

Photographs will be taken from the patients using a 12.1 mega pixel Cannon camera which has a lens zoom of 15*4.

Secondary outcomes

1

Description

Number of the lesions

Timepoint

At baseline and monthly for one year

Method of measurement

Counting visually

2

Description

Size of the lesions

Timepoint

At baseline and monthly for one year

Method of measurement

Evaluating the photographs taken from the lesions

Intervention groups

1

Description

Tacrolimus ointment (0.1%) manufactured by "Quality Care" which will be rubbed on the lesions once every night for one year. The weekly dosage used will be less

than 100 grams.

Category

Treatment - Drugs

2**Description**

Calcipotriol ointment (0.005%) with the trade name of "Daivonex" manufactured by "Quality Care" which will be rubbed on the lesions once every night for one year. The weekly dose of the ointment will be less than 100 grams to avoid probable hypercalcemia.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Sina Hospital

Full name of responsible person

Dr. Farideh Golfroushan

Street address

Dermatology Word, Sina Hospital, Azadi St.

City

Tabriz

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

Vice Chancellor for Research, Tabriz University of Medical Sciences

Full name of responsible person

Mohammadreza Rashidi

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Golbad Ave., Daneshgah St., Tabriz, Iran

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Tabriz

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice Chancellor for Research, Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

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

Tabriz University of Medical Sciences

Full name of responsible person

Farideh Golfroushan

Position

Dermatologist

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Full name of responsible person

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Position**Other areas of specialty/work****Street address****City**

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Postal code**Phone****Fax****Email**

faegheh.alizadeh@yahoo.com

Web page address

empty

Sharing plan

Informed Consent Form

empty

Deidentified Individual Participant Data Set (IPD)

Clinical Study Report

empty

empty

Study Protocol

Analytic Code

empty

empty

Data Dictionary

Statistical Analysis Plan

empty