# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 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)

**Phone**

+98 41 1541 2101

**Email address**

golfroushanf@tbzmed.ac.ir


**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**
Perifulicular 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

**Street address**

Golbad Ave., Daneshgah St., Tabriz, Iran

**City**

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

**Other areas of specialty/work**

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**Web page address**

## Person responsible for scientific inquiries

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
*empty*
**Study Protocol**
*empty*
**Statistical Analysis Plan**
*empty*
**Informed Consent Form**
*empty*
**Clinical Study Report**
*empty*
**Analytic Code**
*empty*
**Data Dictionary**
*empty*