

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

Clinical trial study in the comparison of topical betametazon versus topical tacrolimus 0.1% in the treatment of vitiligo

Protocol summary

Summary

Objectives: To compare the efficacy of topical betametazon versus topical tacrolimus 0.1% in the treatment of vitiligo Design: Clinical trial study Setting and conduct: Randomized clinical trial study Participants including major eligibility criteria: Sixty patients with vitiligo over 2 years old and less than 30% of body surface area will be evaluated. Intervention: The first group will receive tacrolimus 0.1 % cream and the second group will receive topical betamethasone. Patients during the first 6 months (every month) and in the second six months (every two months) will be examined. Main outcome measures: The efficacy, improvment and side effects of each treatment will be evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201311295605N6**

Registration date: **2014-02-13, 1392/11/24**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-02-13, 1392/11/24

Registrant information

Name

MOHAMAD GOLDUST

Name of organization / entity

Tabriz University of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 41133614711

Email address

medres@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2013-10-01, 1392/07/09

Expected recruitment end date

2014-10-01, 1393/07/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial study in the comparison of topical betametazon versus topical tacrolimus 0.1% in the treatment of vitiligo

Public title

The effect of topical betametazon versus topical tacrolimus 0.1% in the treatment of vitiligo

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with vitiligo over 2 years old and less than 30% of body surface area involved.

Exclusion criteria: Patients with allergy or hypersensitivity to macrolides; Pregnant and lactating women; Patients with immune deficiency and patients who had received vitiligo medications less than 6 months ago

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size:

Randomization (investigator's opinion)

Randomized

Randomization description

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

Ethic committee of Tabriz university of medical sciences

Street address

5166614711, University street, Tabriz, Iran

City

Tabriz

Postal code

5166614711

Approval date

2013-09-11, 1392/06/20

Ethics committee reference number

9098

Health conditions studied

1

Description of health condition studied

Vitiligo

ICD-10 code

L80

ICD-10 code description

Vitiligo

Primary outcomes

1

Description

Severity of vitiligo skin lesion

Timepoint

6 month

Method of measurement

Clinical assesment

Secondary outcomes

empty

Intervention groups

1

Description

In the intervention group, 30 patients will receive tacrolimus 0.1 % cream and during the first 6 months (every month) and in the second six months (every two months) will be examined.

Category

Treatment - Drugs

2

Description

In the control group, 30 patients will receive topical betamethasone and during the first 6 months (every month) and in the second six months (every two months) will be evaluated.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina hospital

Full name of responsible person

Street address

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz university of medical sciences

Full name of responsible person

Ramin Mirmohammadi

Street address

5166614711, University street, 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

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

Ramin Mirmohammadi

Position

Resident in dermatology

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

5166614711, University street, Tabriz, Iran

City

Tabriz

Postal code

5166614711

Phone

+98 41 1545 2206

Fax

+98 41 1336 8805

Email

ramin.rms@gmail.com

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

Tabriz university of medical sciences

Full name of responsible person

Shahla Babaei nejad

Position

Associate professor in dermatology

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

5166614711, University street, Tabriz, Iran

City

Tabriz

Postal code**Phone**

+41 15453368805

Fax**Email**

drshbabaie@yahoo.com

Web page address**Person responsible for updating data****Contact****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*