

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effect of 0.1% tacrolimus ointment with 0.5% timolol solution in the treatment of Post Acne erythema

Protocol summary

Study aim

The main aim of the study is to compare the effect of 0.1% tacrolimus ointment with 0.5% timolol solution in the treatment of post-acne erythema.

Design

A controlled, parallel-group, single-blind, randomized phase 3 clinical trial will be conducted on 86 patients with post-acne erythema. The drawing card method will be used for randomization.

Settings and conduct

The study will be performed at the Farshchian (Sina) hospital, Hamadan City, on patients with post-acne erythema. Patients will be randomly assigned to two treatment groups: 0.1% tacrolimus topical ointment and 0.5% timolol maleate solution. The severity of erythema with a photo image of the lesion site based on the criteria of clinical evaluation of erythema, before treatment, at the end of the 4th 8th week of treatment, will be checked and compared. Groups with codes A and B will be sent to the analyst and after analyzing the results, the codes will be revealed (single blind).

Participants/Inclusion and exclusion criteria

Patients with acne vulgaris, over 18 years of age and declaration of consent to participate in the study. Conditions for not entering the study: history of using anti-acne drugs within 3 months before the treatment process, history of allergy to tacrolimus and timolol, pregnancy and breastfeeding, bronchial asthma, severe COPD, sinus bradycardia, 2nd and 3rd degree heart block and heart failure

Intervention groups

One group of patients will be treated with 0.1% tacrolimus topical ointment and the other group will be treated with 0.5% timolol maleate eye solution. Both groups will use the drug once a night for 8 weeks

Main outcome variables

The severity of erythema; side effects of treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151123025202N33**

Registration date: **2023-10-27, 1402/08/05**

Registration timing: **prospective**

Last update: **2023-10-27, 1402/08/05**

Update count: **0**

Registration date

2023-10-27, 1402/08/05

Registrant information

Name

Abbas Moradi

Name of organization / entity

Hamedan University of Medical Of Science

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-22, 1402/09/01

Expected recruitment end date

2024-11-21, 1403/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of 0.1% tacrolimus ointment with 0.5% timolol solution in the treatment of Post Acne erythema

Public title

The effect of tacrolimus ointment and timolol solution in the treatment of post-acne erythema

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age above 18 years Consent to participate in the study

Exclusion criteria:

History of allergy to tacrolimus and timolol History of using anti-acne drugs within 3 months before the treatment process Pregnant and lactating mothers bronchial asthma, severe COPD, sinus bradycardia, 2nd and 3rd degree heart block and heart failure

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Data analyser

Sample size

Target sample size: **86**

Randomization (investigator's opinion)

Randomized

Randomization description

We made 86 cards and write letter TA on 43 for tacrolimus and on the other 43 letter TI for the timolol group. Then put them inside the envelope with aluminum wrap and put in a box. At the time of patient arrival, one of the envelopes randomly will be selected and open it, based on selected letter (TA or TI) patients will be assigned to tacrolimus or timolol group

Blinding (investigator's opinion)

Single blinded

Blinding description

The person analyzing the data will analyze the groups as A and B and will be blind of the type of prescription drugs. A and B codes will be disclosed after the statistical analysis is completed.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

ethics committee of Hamedan University of medical science

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Shahid Fahmide Ave

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Approval date

2023-10-19, 1402/07/27

Ethics committee reference number

IR.UMSHA.REC.1402.479

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

Acne vulgaris

ICD-10 code

L70.0

ICD-10 code description

Acne vulgaris

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

Erythema

Timepoint

Before treatment, at the end of week 4 and at the end of week 8 of treatment

Method of measurement

Take a picture of lesions and and compare based on Clinical Erythema Assessment scale by dermatologist

Secondary outcomes**1****Description**

Side effects of itching, burning, scaling and redness

Timepoint

4th and 8th week of treatment

Method of measurement

Clinical examination and asking the patient about complications

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

Intervention group: Tacrolimus ointment 0.1% will be used topically once a night for 8 weeks.

Category

Treatment - Drugs

2

Description

Intervention group: 0.5% timolol maleate solution will be used topically once a night for a period of 8 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Fashchian (Sina) Hospital

Full name of responsible person

Dr. Mohammad Jamshidi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

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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

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Abbas Moradi

Position

MSc in epidemiology/ Community Medicine MS

Latest degree

Master

Other areas of specialty/work

Epidemiology

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Person responsible for updating data**Contact****Name of organization / entity**

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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

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

All data can be shared except for authors names

When the data will become available and for how long

From 2024 onwards it is permissible

To whom data/document is available

Clinical professionals and Researchers in all fields

Under which criteria data/document could be used

To develop research and science

From where data/document is obtainable

Correspond to the email address of the scientific responsible for the study

What processes are involved for a request to access data/document

Send and receive email

Comments