Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 (s̊ingle 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, prenancy 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)

Phone

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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 TA) 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

Street address
Shahid Fahmide Ave

City
Hamadan

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Hamadan

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6517838677

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
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Web page address
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
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Position
MSc in epidemiology/ Comunity Medicine MS
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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