

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jul 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)

##### Phone

+98 81 3838 0097

##### Email address

a.moradi@umsha.ac.ir

##### 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

## Street address

Shahid Fahmide Ave

## City

Hamadan

## Province

Hamadan

## Postal code

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

**Street address**

Mirzadeh Eshghi

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838736

**Phone**

+98 81 3264 0030

**Email**

sina@umsha.ac.ir

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr Reza Shokohi

**Street address**

Shahid Fahmideh Ave

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838677

**Phone**

+98 81 3838 0717

**Fax**

+98 81 3838 0130

**Email**

vc\_research@umsha.ac.ir

**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

**Full name of responsible person**

Abbas Moradi

**Position**

MSc in epidemiology/ Community Medicine MS

**Latest degree**

Master

**Other areas of specialty/work**

Epidemiology

**Street address**

Community medicine department, Medical School, Shahid Fahmideh Ave

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838736

**Phone**

+98 81 3838 0557

**Fax**

**Email**

a.moradi@umsha.ac.ir

**Web page address**

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr Mohammad Jamshidi

**Position**

Associated professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dermatology

**Street address**

Mirzadeh Eshghi

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838736

**Phone**

+98 81 3264 0030

**Email**

jamshidim84@yahoo.com

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

Hamedan University of Medical Sciences

**Full name of responsible person**

Abbas Moradi

**Position**

Coach

**Latest degree**

Master

**Other areas of specialty/work**

Epidemiology

**Street address**

Shahid Fahmideh Ave

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838736

**Phone**

+98 81 3838 0572

**Fax**

+98 81 3838 0208

**Email**

a.moradi@umsha.ac.ir

**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**