

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The evaluation of effect of Finasteride microemulsion gel in the treatment of men with mild to moderate acne

Protocol summary

Study aim

The objective of this randomized, double-blind clinical trial is evaluation of the effect of Finasteride microemulsion gel in the treatment of men with mild to moderate acne.

Design

In this study, 48 men with mild to moderate acne will be assigned into the study randomly and the subjects will be divided into two groups A and B randomly. Inclusion criteria of the study is male patients and patients with mild to moderate acne. Exclusion criteria of the study is topical or systemic 5 α -reductase enzyme inhibitors drugs use; topical and systemic corticosteroids use; use of Isotretinoin over the past year; history of allergy to any topical or systemic drugs used.

Settings and conduct

Patients will be evaluated by a physician in terms of clinical manifestations of acne (number of lesions, acne severity, patient satisfaction). The two groups will be followed up for 3 months. Finasteride microemulsion gel twice in a day and 1% Clindamycin phosphate topical gel twice in a day will be administered for three months for group (A) and 1% Clindamycin phosphate topical gel twice in a day will be administered for three months for group (B). If any complications are detected, the patient will be excluded from the study. then two weeks, one month, and three months after the intervention will be followed up respectively.

Participants/Inclusion and exclusion criteria

Inclusion criteria of the study is male patients and patients with mild to moderate acne. Exclusion criteria of the study is topical or systemic 5 α -reductase enzyme inhibitors drugs use; topical and systemic corticosteroids use; use of Isotretinoin over the past year; history of allergy to any topical or systemic drugs used.

Intervention groups

Finasteride microemulsion gel twice in a day and 1% Clindamycin phosphate topical gel twice in a day will be administered for three months for group (A) and 1%

Clindamycin phosphate topical gel twice in a day will be administered for three months for group (B).

Main outcome variables

Patients will be examined for acne clinical examinations then two weeks, one month, and three months after the intervention will be followed up respectively.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160318027097N8**

Registration date: **2018-01-12, 1396/10/22**

Registration timing: **registered_while_recruiting**

Last update: **2018-01-12, 1396/10/22**

Update count: **0**

Registration date

2018-01-12, 1396/10/22

Registrant information

Name

Dr Faramarz Darghahi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 45 3351 2000

Email address

mj.naghizadeh@arums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-05, 1396/10/15

Expected recruitment end date

2018-04-04, 1397/01/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The evaluation of effect of Finasteride microemulsion gel in the treatment of men with mild to moderate acne

Public title

Effect of Finasteride gel in the treatment of acne

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Male patients; Patients with mild to moderate acne.

Exclusion criteria:**Age**

From **10 years** old to **70 years** old

Gender

Male

Phase

2-3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization is simple, individual and using a random number table in this study. Patients who will admitted on odd days, will be assigned into group A and patients who will admitted on even days, will be assigned into group B. In this study, participants, researchers are unaware of prescription drugs.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this double-blind study, participants, researchers are unaware of prescription drugs.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Tabriz University of Medical

Sciences

Street address

Tabriz University of Medical Sciences, Daneshgah Avenue, Tabriz, East Azarbaijan, Iran

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Tabriz

Province

East Azarbaijan

Postal code

5163639888

Approval date

2017-09-20, 1396/06/29

Ethics committee reference number

IR.TBZMED.REC.1396.716

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

Acne

ICD-10 code

L70

ICD-10 code description

Acne

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

The acne clinical manifestations

Timepoint

Before the intervention, 2 weeks, 1 month, 3 months after the intervention

Method of measurement

Clinical examinations

Secondary outcomes

empty

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

Intervention group: Finasteride microemulsion topical gel, twice in a day and 1% Clindamycin phosphate topical gel, twice in a day for three months

Category

Treatment - Drugs

2**Description**

Control group: 1% Clindamycin phosphate topical gel, twice in a day for three months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina hospital

Full name of responsible person

Dr Elham Nohchami

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Hassan Soleimanpour

Street address

Vice chancellor for research, Tabriz University of Medical Sciences, Daneshgah Avenue, Tabriz, East Azarbaijan, Iran

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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

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Dr Mehdi Amirnia

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

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Person responsible for updating data

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Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

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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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Total potential data after unidentifiable individuals

When the data will become available and for how long

Start the access period from 2019

To whom data/document is available

Researchers in academic and scientific institutions

Under which criteria data/document could be used

Data can be used for scientific and research studies.

From where data/document is obtainable

Dr Elham Nohchami; Dermatology Assistant;

Naghizadeh73@yahoo.com

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

After receiving the request email, data files will be sent in less than a week.

Comments