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 5α-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 5α-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 Azarbayjan, Iran
City
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
Befor 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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Tabriz University of Medical Sciences, Daneshgah Avenue, Tabriz, East Azarbayjan, Iran

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naghizadeh73@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Hassan Soleimanpour

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Vice chanscellor for research, Tabriz University of Medical Sciences, Daneshgah Avenue, Tabriz, East Azarbayjan, 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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Tabriz University of Medical Sciences, Daneshgah Avenue, Tabriz, East Azarbayjan, Iran

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Person responsible for scientific inquiries

Contact

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Dr Efat Khodayan

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Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr Elham Nohchami

Position

Dermatology Assistant

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