Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jul 2026

Comparison of efficacy of topical combination solution of salicylic acid 2% and erythromycin 4% with topical solution of erythromycin 4% alone in mild to moderate acne vulgaris treatment; double-blinded randomized clinical trial

Protocol summary

Summary

To compare the efficacy of topical combination solution of salicylic acid 2% and erythromycin 4% with topical solution of erythromycin 4% alone in mild to moderate acne vulgaris treatment, 50 patients with age range of 11-30 y/o, from both gender (male & female) are placed in tow groups (A&B) with simple randomization method. Patients under 11 y/o and over 30 y/o, using of topical or systemic steroids, using of anti-androgens, using of anti-acne drugs during previous month, having other face dermatosis and systemic acne accelerator diseases such as, PCO, are the exclusion criteria. Patients with mild to moderate acne, age rang of 11-30 y/o, patient's satisfaction, lack other face dermatosis, lack of systemic acne accelerator diseases are the inclusion criteria. In one group combination of 4 grams erythromycin and 2 grams salicylic acid in 10 cc propylene glycol and alcohol 70 degrees to the volume of the overall 100 cc, and in other group combination of 4 grams erythromycin in 10 cc propylene glycol and alcohol 70 degrees to the volume of the overall 100cc will be prescribed. Patients will be advised to apply the solution on their face, twice daily, with slight rubbing. The treatment duration will be 12 weeks. All patients will be recommended to use of oil-free sunscreen during the day. The patients will be visited at 15 day period for evaluation of reducing the number of lesions (comedons, papules & pustules), acne severity index,patient's satisfaction and side effects of treatment. In the end of study data will be collected and analyzed with statistical methods.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201010094269N3**

Registration date: **2011-10-19, 1390/07/27**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-10-19, 1390/07/27

Registrant information

Name

Farideh Golfroushan

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Deputy for research, Tabriz University of Medical Sciences and Health Services

Expected recruitment start date

2010-10-23, 1389/08/01

Expected recruitment end date

2012-01-21, 1390/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of efficacy of topical combination solution of salicylic acid 2% and erythromycin 4% with topical solution of erythromycin 4% alone in mild to moderate acne vulgaris treatment; double-blinded randomized clinical trial

Public title

Effect of combined topical solution 2% salicylic acid and erythromycin 4% with erythromycin 4% topical solution in the treatment of mild to moderate acne vulgaris

Purpose

Treatment

Inclusion/Exclusion criteria

Exclusion criteria:patients who are using topical or systemic steroids ; patients who are using contraceptive pills (anti-androgen); patients who are used topical or oral anti-acne medications, during the previous month, even include natural and UV light and Herbal and traditional acne treatments; if there are other face dermatosis and other systemic acne accelerator diseases such as Cushing's syndrome, PCO,adrenal hyperplasia, acquired and innate immun deficiency, steroid acne and acneiform lesions and ....; patient's dissatisfaction ;if there are more than 20 inflammatory lesions (papules and pustules) and three nodules or cysts on one side of the face ; patients with acne excoree ;age under 11 y/o andover 30 y/o ;if there is an inflammatory disease,except acne, on the face such as contact dermatitis, allergic or seborrheic dermatitis and...
Inclusion criteria:patients with mild to moderate acne in age range 11-30 years old ; patients who have maximum 20 inflammatory lesions (papules &pustule) on one side of the face and have not more than three nodules or cysts on the same side of the face; lack of other face dermatosis such as contact dermatitis, allergic or seborrheic dermatitis and ...; having patient's satisfaction ; lack of other systemic acne accelerator diseases such as Cushing's syndrome, PCO, adrenal hyperplasia, acquired and innate immun deficiency, steroid acne and acneiform lesions and.... ; patients who are not used of oral or topical anti-acne medications, during the previous month, even include natural and UV light, herbal and traditional acne treatments.

Age

From **11 years** old to **30 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tabriz University of Medical Science and Health Services

Street address

Deputy of Tabriz University of Medical Sciences and Health Services, Golgasht Street, Tabriz, Iran

City

Tabriz

Postal code

Approval date

2010-10-23, 1389/08/01

Ethics committee reference number

6996/4/5

Health conditions studied

1

Description of health condition studied

Mild to modrate acne vulgaris

ICD-10 code

L70.0

ICD-10 code description

Acne vulgaris

Primary outcomes

1

Description

Acne severity index

Timepoint

Every15 days

Method of measurement

History, physical examination, counting and statistical evaluation

Secondary outcomes

1

Description

Age

Timepoint

Every 15 days

Method of measurement

History

2

Description
Gender
Timepoint
Every 15 days
Method of measurement
History

3

Description
Comedon
Timepoint
Every 15 days
Method of measurement
Physical examination and counting

4

Description
Papule
Timepoint
Every 15 days
Method of measurement
Physical examination and counting

5

Description
Pustule
Timepoint
Every 15 days
Method of measurement
Physical examination and counting

6

Description
Total numbers of lesions
Timepoint
Every 15 days
Method of measurement
Physical examination and counting

7

Description
Patient's satisfaction
Timepoint
Every 15 days
Method of measurement
History

8

Description
Side efect of treatment
Timepoint
Every 15 days
Method of measurement
History and physical examination

Intervention groups

1

Description
Intervention group: combination of erythromycin 4 g and salicylic acid in 10 cc propylene glycol and alcohol 70 degrees to the volume of the overall 100 cc will apply to the face with cotton applicator twice aday for 3 months
Category
Treatment - Drugs

2

Description
Control group: combination of erythromycin 4 g in 10 cc propylene glycol and alcohol 70 degrees to the volume of the overall 100 cc will be apply to the face with cotton applicator twice aday for 3 months
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Sina Educational and Treatment Center ,Tabriz University of Medical Science and Health Services
Full name of responsible person
Street address
City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Deputy of Tabriz University of Medical Sciences and Health Services
Full name of responsible person
Farideh Golfroushan
Street address
Sina Educational and Treatment Center- Department of Dermatology
City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Deputy of Tabriz University of Medical Sciences and Health Services
Proportion provided by this source
100
Public or private sector
empty

Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Deputy of Tabriz University of Medical Sciences and Health Services
Full name of responsible person
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty