Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of therapeutic effects of topical Isotretinoin %0.05 with Clindamycine %1 in the treatment of papulo pustular acne vulgaris

Protocol summary

Summary

The purpose of this study is to compare therapeutic effects of topical Isotretinoin %0.05 with Clindamycine %1 in the treatment of papulo pustular acne. We will include patients aged between 11 to 30 years and will exclude pregnant and lactating women and patients who have used anti acne drugs in recent month. We will prescribe topical Isotretinoin gel in 30 patients every night and topical Clindamycin in 30 other patients twice daily for 90 days. Each patient will be examined at the onset and every 30 days.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201105032581N2**
Registration date: **2011-11-26, 1390/09/05**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2011-11-26, 1390/09/05

Registrant information

Name
Hamide Herizchi
Name of organization / entity
Tabriz University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Tabriz Univercity of Medical Sciences

Expected recruitment start date

2011-08-10, 1390/05/19

Expected recruitment end date

2012-05-08, 1391/02/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of therapeutic effects of topical Isotretinoin %0.05 with Clindamycine %1 in the treatment of papulo pustular acne vulgaris

Public title

Comparison of therapeutic effects of topical Isotretinoin %0.05 and Clindamycine %1 in the treatment of acne vulgaris

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with mild to moderate acne between 11 to 30 years old; patients who have at most 20 inflammatory lesion (papule, pustule) in one side of face and don't have more than 3 nodule or cyst in the same side; tendency to intend in study. Exclusion criteria: pregnant and lactating women; patients who have used topical anti acne drugs in the recent month; patients who have used oral anti acne drugs in past 2 months; having any other facial skin disease other than acne; having sever nodulocystic acne; consumption of acne inducing drugs such as lithium, oral steroid, vit B12, brom and iodide drugs; patients who have more than 20 inflammatory lesion (papule, pustule) in one side of face and have more than 3 nodule or cyst in the same side.

Age

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

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Tabriz Univercity of Medical Sciences

Street address
Vice Chancellor forresearch, 3rd floor, centural office, Tabriz Univercity of Medical Sciences, Golgasht st.

City
Tabriz

Postal code

Approval date
2011-04-18, 1390/01/29

Ethics committee reference number
5/4/748

Health conditions studied

1

Description of health condition studied
mild to moderate acne vulgaris

ICD-10 code
L70.0

ICD-10 code description
Acne vulgaris

Primary outcomes

1

Description
severity

Timepoint
every 30 days

Method of measurement
History and clinical examination

Secondary outcomes

1

Description
pustules

Timepoint
every 30 days

Method of measurement
clinical examination

2

Description
total acne lesions

Timepoint
every 30 days

Method of measurement
clinical examination

3

Description
index of acne severity

Timepoint
every 30 days

Method of measurement
clinical examination, statistical measurment

4

Description
patient satisfaction

Timepoint
every 30 days

Method of measurement
Questionnare

5

Description
comedones

Timepoint
every 30 days

Method of measurement
clinical examination

Intervention groups

1

Description
Group A: topical Isotretinon gel 0.05% every night on acne lesions for 3months

Category
Treatment - Drugs

2

Description
Group B: 1% Clindamycine solution twice daily on acne lesion for 3months
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Educational and treatment center of Sina
Full name of responsible person
Dr. Herizchi Hamide
Street address
City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr. Meshkini Ali
Street address
Tabriz University of Medical Sciences, Gholghasht st.
City
Tabriz
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
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

Person responsible for scientific inquiries

Contact
Name of organization / entity
Vice chancellor for research of Tabriz Univercity of Medical Sciences
Full name of responsible person
Dr. Herizchi Hamide
Position
Skin Disease Specialist / assistant
Other areas of specialty/work
Street address
Educational and treatment center of Sina
City
Tabriz
Postal code
Phone
+98 41 1336 4160
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Email
herizchih@tbzmed.ac.ir
Web page address

Person responsible for updating data

Contact

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