

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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

Country

Iran (Islamic Republic of)

Phone

+98 41 1336 4650

Email address

herizchih@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Tabriz University 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 University of Medical Sciences

Street address

Vice Chancellor for research, 3rd floor, central office,
Tabriz University 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 measurement

4

Description

patient satisfaction

Timepoint

every 30 days

Method of measurement

Questionnaire

5

Description

comedones

Timepoint

every 30 days

Method of measurement

clinical examination

Intervention groups

1

Description

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

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 University 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

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Phone

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Fax

Email

herizchi@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