Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Safety and efficacy comparison of gel and emulgel formulations of tretinoin 0.025% and clindamaycin 1.2% for treatment of mild to moderate acne vulgaris

Protocol summary

Study aim

Safety and efficacy comparison of gel and emulgel formulations of tretinoin 0.025% and clindamaycin 1.2% for treatment of mild to moderate acne vulgaris

Design

The study is a phase 2, parallel treatment-control clinical trial. Sample size is 20. The study is randomized and double blinded. Randomization is done simply using a blind card, so names of the formulations are written on the same cards then each card is randomly selected for any side of the face.

Settings and conduct

The study will be performed in Center for the Study and Research of Diseases of the Skin and Leprosy, 20 volunteers with acne vulgaris will be selected and enrolled in the study after signing consent form. Volunteers will be taught to use " of Tretinoin 0.025% and Clindamaycin 1.2% for 8 weeks once in a day. Before intervention and at the end of 4 and 8 weeks later changing in skin will be measured. This study is double blinded. The clinicians who performed the clinical assessments and objective device analysis are completely blinded to the treatment type. Participants will receive the treatment according to the randomization list by an independent assistant.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Male or female aged 16-40 years, Mild to moderate inflammatory or non-inflammatory acne lesions (grade 1 to 3 according to the table) on face Exclusion criteria: People with allergies to formulation ingredients, Nodular or cystic lesions that represent a severe type of acne vulgaris

Intervention groups

Intervention group: Topical use of emulgel formulations of tretinoin 0.025% and clindamaycin 1.2% for 8 weeks once in a day Control group: Topical use of gel formulations of tretinoin 0.025% and clindamaycin 1.2% for 8 weeks once in a day

Main outcome variables

Evaluate of acne severity index by a physician

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150101020514N13**
Registration date: **2021-12-13, 1400/09/22**
Registration timing: **prospective**

Last update: **2021-12-13, 1400/09/22**
Update count: **0**

Registration date

2021-12-13, 1400/09/22

Registrant information

Name

Alireza Firooz

Name of organization / entity

Tehran University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 21 8897 8190

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firozali@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-22, 1400/10/01

Expected recruitment end date

2022-10-23, 1401/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Safety and efficacy comparison of gel and emulgel formulations of tretinoin 0.025% and clindamaycin 1.2% for treatment of mild to moderate acne vulgaris

Public title

Safety and efficacy comparison of gel and emulgel formulations of Tertinoin and Clindamaycin for treatment of mild to moderate acne vulgaris

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Male or female aged 16-40 years Mild to moderate inflammatory or non-inflammatory acne lesions (grade 1 to 3 according to the table) on face

Exclusion criteria:

People with allergies to formulation ingredients Nodular or cystic lesions that represent a severe type of acne vulgaris

Age

From **16 years** old to **40 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is done simply using a blind card, so names of the formulations are written on the same cards then each card is randomly selected for any side of the face

Blinding (investigator's opinion)

Double blinded

Blinding description

Products of both groups are packed in similar boxes with different numeric code. In case of assessor blinding, the randomization list is given to a third person. The clinicians who performed the clinical assessments and objective device analysis are completely blinded to the treatment type. participants will receive the treatment according to the randomization list by an independent assistant.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Room 105 , 5th floor, Central construction of Tehran University of Medical Sciences, Ghods intersection, Keshavarz blvd.

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2021-05-31, 1400/03/10

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1400.199

Health conditions studied

1

Description of health condition studied

Acne vulgaris

ICD-10 code

L70.0

ICD-10 code description

Acne vulgaris

Primary outcomes

1

Description

Evaluate the improvement of acne severity index by a physician

Timepoint

Before intervention, 4 and 8 weeks after the start of use

Method of measurement

An independent dermatologists perform evaluation and scoring with the help of photos based on the percentage of improvement in acne using:(0=normal skin, 2=skin is almost clear, 3=some non-inflammatory lesions are present, 4=non-inflammatory lesions are predominant, with multiple inflammatory lesions. 5=highly inflammatory lesions predominate)

Secondary outcomes

1

Description

Trans Epidermal Water Loss

Timepoint
Before intervention, 4 and 8 weeks after the start of use
Method of measurement
Tewameter

2

Description
Skin sebum
Timepoint
Before intervention, 4 and 8 weeks after the start of use
Method of measurement
Sebumeter

Intervention groups

1

Description
Intervention group: Topical application of compounding emulgel (not industrial) containing tretinoin 0.025% and clindamaycin 1.2% on acne lesions of one side of the face (randomly) once a day (before sleeping), for 8 weeks
Category
Treatment - Drugs

2

Description
Control group: Topical application of compounding gel (not industrial) containing tretinoin 0.025% and clindamaycin 1.2% on acne lesions of one side of the face (randomly) once a day (before sleeping), for 8 weeks
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Center for research and training in skin diseases and leprosy
Full name of responsible person
Aniseh Samadi
Street address
No. 415, Shahid Naderi (Soheil) Street, Taleqani Avenue
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Jarf Andishan Nnavid Salamat knowlage based company (JANUS)
Full name of responsible person
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No. 415, Shahid Naderi (Soheil) Street, Taleqani Avenue
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Email
headoffice@januspharma.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Jarf Andishan Nnavid Salamat knowlage based company (JANUS)
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Aniseh Samadi
Position
Manger of clinical study unit
Latest degree
Ph.D.
Other areas of specialty/work
Skin Biometrics
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable