Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Safety and efficacy assessment of “Synskin Acnes 2 acute phase cream” and “Synskin Acnes 3 chronic phase cream” for treatment of mild to moderate acne vulgaris

Protocol summary

Study aim

Safety and efficacy assessment of “Synskin Acnes 2 acute phase cream” and “Synskin Acnes 3 chronic phase cream” for treatment of mild to moderate acne vulgaris

Design

Single group, phase 2, before -after clinical study. sample size is 20. The study is not randomized.

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 “Synskin Acnes 2 acute phase cream” for 2 weeks and “Synskin Acnes 3 chronic phase cream” from 3th to10th week twice a day. Before intervention and at the end of 2,6 and10 weeks later changing in skin will be measured. This study is not blinded.

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

Topical use of “Synskin Acnes 2 acute phase cream” (Contains anti-acne compounds such as Tea tree extract, Niacin amid, Vitamin A, etc..) for 2 weeks twice a day and then “Synskin Acnes 3 chronic phase cream”(Contains Niacin amid, Vitamin A,Canadian willow extract, etc..) for 8 weeks.

Main outcome variables

Evaluate the improvement of acne severity index by a physician based on: 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

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190210042676N14**
Registration date: **2021-06-11, 1400/03/21**
Registration timing: **prospective**

Last update: **2021-06-11, 1400/03/21**
Update count: **0**

Registration date

2021-06-11, 1400/03/21

Registrant information

Name

Aniseh Samadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8897 2220

Email address

a_samadi@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-22, 1400/04/01

Expected recruitment end date

2022-02-20, 1400/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Safety and efficacy assessment of “Synskin Acnes 2 acute phase cream” and “Synskin Acnes 3 chronic phase cream” for treatment of mild to moderate acne vulgaris

Public title

Safety and efficacy assessment of Synskin “ Acnes 2 cream” and “ Acnes 3 cream” for treatment of acne

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

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

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

Research and Technology Dept, 6th floor, Central Organization of the University, Ghods St., Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2021-02-01, 1399/11/13

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1399.1038

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, 2, 6 and 10 weeks after the start of use

Method of measurement

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, 2, 6 and 10 weeks after the start of use

Method of measurement

Tewameter

2

Description

Skin sebum

Timepoint

Before intervention, 2, 6 and 10 weeks after the start of use

Method of measurement

Sebumeter

Intervention groups

1

Description
Intervention group: Topical use of “Synskin Acnes 2 acute phase cream” (Contains anti-acne compounds such as Tea tree extract, Niacin amid, Vitamin A, etc..) for 2 weeks twice a day and then “Synskin Acnes 3 chronic phase cream”(Contains Niacin amid, Vitamin A,Canadian willow extract, etc..) 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
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No. 415, Shahid Naderi (Soheil) St., Taleqani Ave.
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1416613675
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+98 21 8897 0658
Email
dermalab@tums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran Avandfar Company
Full name of responsible person
Nader Soltani Hoseini
Street address
No.80 ,Baqerkhan Ave. ,Sattarkhan St.
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Tehran
Postal code
1441764181
Phone
+98 21 6642 2655
Email
info@iranbath.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran Avandfar Company
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 scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Alireza Firooz
Position
Professor of dermatology
Latest degree
Specialist
Other areas of specialty/work
Dermatology
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Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Maryam Ahmadi

Position

Research Expert

Latest degree

Master

Other areas of specialty/work

Clinical Research

Street address

No. 415, Shahid Naderi (Soheil) St., Taleqani Ave.

City

Tehran

Province

Tehran

Postal code

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