

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jun 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 to 10th week twice a day. Before intervention and at the end of 2, 6 and 10 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

#### Street address

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

#### City

Tehran

#### Province

Tehran

#### Postal code

1416613675

#### Phone

+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.

#### City

Tehran

#### Province

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

#### City

Tehran

#### Province

Tehran

#### Postal code

1416613675

#### Phone

+98 21 8896 0880

#### Email

aniseh\_samadi@yahoo.com

## 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

#### Street address

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

#### City

Tehran

#### Province

Tehran

#### Postal code

1416613675

**Phone**

+98 21 8897 7921

**Email**

firozali@sina.tums.ac.ir

## 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**

1416613675

**Phone**

+98 21 8897 0658

**Email**

ahmadi.maryam648@gmail.com

## 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