Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Safety and efficacy assessment of Synskin triple action eye contour cream (invisible) for reducing periorbital wrinkle, dark circle and puffiness

Protocol summary

Study aim

Safety and efficacy assessment of Synskin triple action eye contour cream (invisible) for reducing periorbital wrinkle, dark circle and puffiness

Design

It is a phase II interventional study as a non-randomized and before-after clinical study.20 healthy adult volunteers will participate enrolled in the study after signing informed consent.

Settings and conduct

The study will be conducted in Center for Research & Training in Skin Diseases and Leprosy. Participants will receive the eye contour cream, twice a day for 8 weeks on periorbital area. The assessments of area, volume and depth of periorbital wrinkles as well as skin biophysical parameters (skin hydration, trans epidermal water loss, erythema, melanin and skin elasticity) will be performed before intervention, 4 and 8 weeks after treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Male or female aged 30-60 years,The presence of periorbital wrinkle, dark circle and puffiness, No change in life style during the study, Signed informed consent knowingly Exclusion criteria: Critical untreated systemic disease in medical history, Any facial rejuvenation treatment, including treatment with topical or oral products or supplements during the last four weeks, Any facial rejuvenation treatment including rejuvenation devices or surgical procedures and Botox injections during the last four months, Sensitivity and allergy to the components of the formulation, Use of any eye cream or eye sunscreen cream during the last four weeks, Use of anti-wrinkle or brightening cleansers over the past four weeks, Pregnancy or lactation

Intervention groups

Using Synskin triple action eye contour cream twice a day for 8 weeks

Main outcome variables

Assessment of periorbital wrinkle, dark circle and puffiness by three independent physician using 0-3 scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210130050179N1**
Registration date: **2021-02-20, 1399/12/02**
Registration timing: **registered_while_recruiting**

Last update: **2021-02-20, 1399/12/02**
Update count: **0**

Registration date

2021-02-20, 1399/12/02

Registrant information

Name

Taraneh Yazdanparast

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8897 2220

Email address

drtaraneh@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-14, 1399/11/26

Expected recruitment end date

2021-06-16, 1400/03/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Safety and efficacy assessment of Synskin triple action eye contour cream (invisible) for reducing periorbital wrinkle, dark circle and puffiness

Public title

Safety and efficacy assessment of Synskin triple action eye contour cream

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Male or female aged 30-60 years The presence of periorbital wrinkle, dark circle and puffiness No change in life style during the study Signed informed consent knowingly

Exclusion criteria:

Critical untreated systemic disease in medical history Any facial rejuvenation treatment, including treatment with topical or oral products or supplements during the last four weeks Any facial rejuvenation treatment including rejuvenation devices or surgical procedures and Botox injections during the last four months Sensitivity and allergy to the components of the formulation Use of any eye cream or eye sunscreen cream during the last four weeks Use of anti-wrinkle or brightening cleansers over the past four weeks Pregnancy or lactation

Age

From **30 years** old to **60 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

2021-02-04, 1399/11/16

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1399.1052

Health conditions studied

1

Description of health condition studied

periorbital wrinkle, dark circle and puffiness

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Assessment of periorbital wrinkle, dark circle and puffiness by three independent physician using 0-3 scale

Timepoint

Before intervention and 4 and 8 weeks after treatment

Method of measurement

Three independent dermatologists perform evaluation and scoring with the help of right and left lateral view and full face photos based on the percentage of improvement in periorbital wrinkles, dark circle and puffiness using scale 0 to 3 (0 = no improvement 1 = relative improvement 2 = good improvement 3 = Excellent improvement) .

Secondary outcomes

1

Description

Area, volume and depth of periorbital wrinkle

Timepoint

Before intervention and 4 and 8 weeks after treatment

Method of measurement

Visioface

2

Description

periorbital dark circle grading using Characteristics of Dark circles grade

Timepoint

Before intervention and 4 and 8 weeks after treatment

Method of measurement

Research physician will perform clinical assessments according to the Characteristics of Dark circles grade

3

Description

Melanin content

Timepoint

Before intervention and 4 and 8 weeks after treatment

Method of measurement

Mexameter

4

Description

stratum corneum hydration

Timepoint

Before intervention and 4 and 8 weeks after treatment

Method of measurement

Corneometer

5

Description

Trans epidermal water loss

Timepoint

Before intervention and 4 and 8 weeks after treatment

Method of measurement

Tewameter

6

Description

Erythema

Timepoint

Before intervention and 4 and 8 weeks after treatment

Method of measurement

Mexameter

7

Description

Fitzpatrick’s Classification of Facial Wrinkling & degree of Elastosis

Timepoint

Before intervention and 4 and 8 weeks after treatment

Method of measurement

Research physician will perform clinical assessments according to the Fitzpatrick’s Classification

8

Description

Infra-orbital pigmentation severity and degree of lightness

Timepoint

Before intervention and 4 and 8 weeks after treatment

Method of measurement

Visioface

Intervention groups

1

Description

Intervention group: Using Synskin triple action eye contour cream twice a day 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

Taraneh Yazdanparast

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

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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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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
Taraneh yazdanparast
Position
Research Physician
Latest degree
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Other areas of specialty/work
Dermatology
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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