

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Clinical evaluation of the safety and effectiveness of the nanofiber under-eye pad containing ketone enzyme to improve surface wrinkles and dark circles under the eyes compared to placebo

Protocol summary

Study aim

Clinical evaluation of the safety and effectiveness of the nanofiber under-eye pad containing ketone enzyme to improve surface wrinkles and dark circles under the eyes compared to placebo

Design

It is a phase II interventional study as a randomized clinical study. 10 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 nanofiber under-eye pad containing ketone enzyme, 30 minutes in a day for 6 days under-eye area. The assessments of dark circle and wrinkle of under eye area as well as skin biophysical parameters (melanin and skin elasticity) will be performed before intervention, 6 and 28 days after treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Male or female aged 18-59 years, Signed informed consent knowingly, The presence of mild to moderate periorbital wrinkle and darkness
Exclusion criteria: Using any eye product within 2 weeks before the intervention, Strict diet in the period of 2 weeks before the intervention, Pregnancy or lactation, Being exposed to strong sunlight during the day

Intervention groups

Intervention group: 30 minutes of using nanofiber under-eye pads containing ketone co-enzyme made by Nanotarpak company for 6 days
Control group: 30 minutes of using a nanofiber under-eye pad without active ingredients for 6 days

Main outcome variables

Assessment of under eye dark circle and wrinkle

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210130050179N9**

Registration date: **2024-02-25, 1402/12/06**

Registration timing: **registered_while_recruiting**

Last update: **2024-02-25, 1402/12/06**

Update count: **0**

Registration date

2024-02-25, 1402/12/06

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

2024-02-20, 1402/12/01

Expected recruitment end date

2024-06-21, 1403/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical evaluation of the safety and effectiveness of the nanofiber undereye pad containing ketone enzyme to improve surface wrinkles and dark circles under the eyes compared to placebo

Public title

Clinical evaluation of the safety and effectiveness of the nanofiber undereye pad to improve surface wrinkles and dark circles under the eyes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Male or female aged 18-59 years Signed informed consent knowingly The presence of mild to moderate periorbital wrinkle and darkness

Exclusion criteria:

Using any eye product within 2 weeks before the intervention Strict diet in the period of 2 weeks before the intervention Pregnancy or lactation Being exposed to strong sunlight during the day

Age

From **18 years** old to **59 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **10**

Randomization (investigator's opinion)

Randomized

Randomization description

After the measurements, the lower area of the right or left eye was used for the use of nanofiber under eye pad containing the active substance (ketone) and the opposite area as a control for using nanofiber under eye pad without the active substance. Randomization is done simply using blind card. In this way, the name of the formulations is written on the same cards and for each of the left or right area, a card is selected randomly.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of The Institute of Pharmaceutical Sciences of Tehran University of Medical Science

Street address

Unit 1-219, 2nd floor, The Institute of Pharmaceutical Sciences, Faculty of Pharmacy, 16 Azar Avenue

City

Tehran

Province

Tehran

Postal code

1417613151

Approval date

2024-01-21, 1402/11/01

Ethics committee reference number

IR.TUMS.TIPS.REC.1402.157

Health conditions studied

1

Description of health condition studied

periorbital wrinkle, dark circle and puffiness

ICD-10 code

R23.4

ICD-10 code description

Changes in skin texture

Primary outcomes

1

Description

Assessment of under eye dark circle and wrinkle

Timepoint

Before intervention and 6 and 28 days after treatment

Method of measurement

Based on GIAS(Global Aesthetic Improvement Scale)

Secondary outcomes

1

Description

Melanin content

Timepoint

fore intervention and 6 and 28 days after treatment

Method of measurement

Mexameter

2

Description

Infra-orbital pigmentation severity and degree of lightness

Timepoint

fore intervention and 6 and 28 days after treatment

Method of measurement

Visioface

Intervention groups

1

Description

Intervention group: 30 minutes of using nanofiber under-eye pads containing ketone co-enzyme made by Nanotarpak company for 6 days

Category

Treatment - Devices

2

Description

Control group: 30 minutes of using a nanofiber under-eye pad without active ingredients for 6 days

Category

Other

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.

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1416613675

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dermalab@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Nano tarpak company

Full name of responsible person

Nasim Gholam Shahbazi

Street address

Unit 8, Exir Building, Nizam Alley, between Jami and Jumhori, Valiasr St.

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Postal code

1138635418

Phone

+98 21 6617 6901

Email

f.rostami.nanopak@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Nano tarpak 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

Ph.D.

Other areas of specialty/work

Dermatology

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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

Subspecialist

Other areas of specialty/work

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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

Undecided - It is not yet known if there will be a plan to make this available

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