Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

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

Protocol summary

Study aim

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

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 undereye 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
Phone
+98 21 8897 0658
Email
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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Tehran
Province
Tehran
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

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Tehran University of Medical Sciences
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Alireza Firooz
Position
Professor of dermatology
Latest degree
Specialist
Other areas of specialty/work
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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
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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