

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Efficacy comparison of 2 tinted and invisible sunscreen products with similar formulation and SPF 50, on reducing skin damage caused by sunlight in the Iranian population with skin type 2 to 4:Single-blind randomized clinical trial

Protocol summary

Study aim

Comparing the effectiveness of tinted and invisible sunscreen products with similar formulations and SPF 50 on reduction of skin damage caused by sun irradiation in Iranian population with skin type 2 to 4

Design

It is a phase II interventional study as a randomized and one-way blind before-after clinical study. 110 adult volunteers with atopic dermatitis will participate in the study after signing informed consent. Randomization is done simply using blind card so that the names of the creams are inserted on the same cards and for each participant a card is selected randomly. Skin factors including skin melanin and Changes in erythema intensity (factor E) and skin lightness (factor L) will be measured before intervention and 8 and 16 weeks after treatment.

Settings and conduct

The study will be conducted in Center for Research & Training in Skin Diseases and Leprosy. Participants will receive tinted and invisible Prime sunscreen products with similar formulations and SPF 50 Cream, third in a day for 8 weeks on whole of face. Due to the difference in appearance of two types of creams, the evaluating person who performs the biophysical tests of the skin and the physician supervising the tests is different from who assigned the creams and therefore the study is outcome assessor blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Healthy people 18 to 60 years old, Signing the consent form for participation in the study
Exclusion criteria: History of any skin disease except acne, allergies and rosacea, Facial skin surgery in the last 2 months, Any systemic disease that affects the skin (diabetes, thyroid disease and etc..)

Intervention groups

Using of tinted and invisible sunscreen products with similar formulations and SPF 50 is used every three hours from 8 AM to 8 PM (4 times in a day)

Main outcome variables

Changes in skin melanin

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210130050179N3**

Registration date: **2022-05-17, 1401/02/27**

Registration timing: **prospective**

Last update: **2022-05-17, 1401/02/27**

Update count: **0**

Registration date

2022-05-17, 1401/02/27

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

2022-05-22, 1401/03/01

Expected recruitment end date

2025-05-22, 1404/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy comparison of 2 tinted and invisible sunscreen products with similar formulation and SPF 50, on reducing skin damage caused by sunlight in the Iranian population with skin type 2 to 4:Single-blind randomized clinical trial

Public title

Efficacy comparison of 2 tinted and invisible sunscreen products with similar formulation and SPF 50, on reducing skin damage caused by sunlight

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Healthy people aged between 18 to 60 years Signing the informed consent form

Exclusion criteria:

History of any skin disease except acne, allergies and rosacea Facial skin surgery in the last 2 months Any systemic disease that affects the skin (diabetes, thyroid disease and etc..)

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **110**

Randomization (investigator's opinion)

Randomized

Randomization description

Block Randomization method will be used to assign samples to each of the tinted and invisible sunscreen groups. At first, the size of the blocks will be considered to be 10, according to the number of samples, 11 blocks will be selected based on a table of random numbers and individuals will be assigned to groups based on their position in the blocks.

Blinding (investigator's opinion)

Single blinded

Blinding description

Due to the difference in appearance of two types of creams, the assessor person who performs the biophysical tests of the skin and the physician supervising the tests are different from who assigned the creams and therefore the study is outcome assessor blind.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee in research of medical school- 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

2021-06-16, 1400/03/26

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1400.287

Health conditions studied**1****Description of health condition studied**

Reduce skin damage caused by sunlight

ICD-10 code

L55

ICD-10 code description

Sunburn

Primary outcomes**1****Description**

Skin melanin

Timepoint

Before intervention and 8 and 16 weeks after treatment

Method of measurement

mexameter

Secondary outcomes**1****Description**

Changes in erythema intensity (factor E) and skin

lightness (factor L)
Timepoint
Before intervention and 8 and 16 weeks after treatment
Method of measurement
Using Visioface device and CSI software

Intervention groups

1

Description
Intervention group: Tinted sunscreen cream will be used every three hours from 8 AM to 8 PM (4 times in a day)
Category
Treatment - Drugs

2

Description
Control group: Invisible sunscreen cream will be used every three hours from 8 AM to 8 PM (4 times in a day)
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
Street address
No. 415, Shahid Naderi (Soheil) Street, Taleqani Avenue
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1416613675
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drtaraneh@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Akhavi laboratory
Full name of responsible person
Farid Akhavi
Street address
Unit 8, No.17, Tavanir Street, Valiasr Street
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Province

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1434875419
Phone
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Email
info@akhavilab.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Akhavi laboratory
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 scientific inquiries

Contact
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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

Master

Other areas of specialty/work

Clinical Research

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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