

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the safety and effectiveness of Nutra moisturizing cream in improving chronic dry skin in sensitive skin

Protocol summary

Study aim

Evaluation of the safety and effectiveness of Nutra moisturizing cream in improving chronic dry skin in sensitive skin

Design

The study is a phase 2-3 clinical trial, split body randomized and double-blind comparison with placebo. Randomization is done simply using blind card.

Settings and conduct

The study will be performed in Center for the Study and Research of Diseases of the Skin and Leprosy, 20 healthy volunteers will be selected and enrolled in the study after signing consent form. Volunteers are taught to use of 25 µL of 2 types of Nutra moisturizing cream produced by Nova pharmed chemia and a placebo cream topically. Blinding the participants will be such that both products will be packed in the same containers, that are distinguished from each other only by code number and name of using area on the packaging. In order to blind the outcome assessor, the randomization list will be provided to a third person and the allocation of formulations to each of the participants' left or right organs will be done after receiving the random code. Before intervention, 4 hours after using and 4 weeks after not using changing in stratum corneum hydration will be measured.

Participants/Inclusion and exclusion criteria

Inclusion criteria: People aged between 18 to 60 years, Bilateral and almost symmetric dryness in upper or lower extremities according to researcher physician, General health, Signing the informed consent form
Exclusion criteria: active smoker, active skin lesion of treatment site, Cutaneous or systemic diseases or any skin condition caused dry skin such as diabetes and hypothyroidism, Currently pregnant or lactating

Intervention groups

Intervention group: Topical use of 25 µL of 2 types of Nutra moisturizing cream produced by Nova pharmed chemia. Control group: Topical use of 25 µL of a placebo

cream.

Main outcome variables

Changing in stratum corneum hydration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210130050179N7**

Registration date: **2023-04-26, 1402/02/06**

Registration timing: **registered_while_recruiting**

Last update: **2023-04-26, 1402/02/06**

Update count: **0**

Registration date

2023-04-26, 1402/02/06

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

2023-04-21, 1402/02/01

Expected recruitment end date

2023-10-23, 1402/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of the safety and effectiveness of Nutra moisturizing cream in improving chronic dry skin in sensitive skin

Public title
Evaluation of the safety and effectiveness of Nutra moisturizing cream in improving dry skin

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
People aged between 18 to 60 years Bilateral and almost symmetric dryness in upper or lower extremities according to researcher physician General health Signing the informed consent form
Exclusion criteria:
active smoker active skin lesion of treatment site Cutaneous or systemic diseases or any skin condition caused dry skin such as diabetes and hypothyroidism Currently pregnant or lactating

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

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **20**

Randomization (investigator's opinion)
Randomized

Randomization description
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 organs a card is selected randomly.

Blinding (investigator's opinion)
Double blinded

Blinding description
Blinding the participants will be such that both products will be packed in the same containers, that are distinguished from each other only by code number and name of using area on the packaging. In order to blind the outcome assessor, the randomization list will be provided to a third person and the allocation of formulations to each of the participants' left or right organs will be done after receiving the random code.

Placebo
Used

Assignment
Single

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

2024-02-21, 1402/12/02

Ethics committee reference number

IR.TUMS.TIPS.REC.1401.118

Health conditions studied

1

Description of health condition studied

Dry skin

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Comparison the change in stratum corneum hydration after using two types of moisturizers and placebo

Timepoint

Before intervention, 4 hours after using and 4 weeks after not using.

Method of measurement

Corneometry

Secondary outcomes

1

Description

Trans Epidermal Water Loss

Timepoint

Before intervention and 1 and 4 hours, 1 and 2 weeks after using

Method of measurement

Tewameter

Intervention groups

1

Description

Intervention group: Topical use of 25 µL of 2 types of Nutra moisturizing cream produced by Nova pharmed chemia.

Category

Treatment - Drugs

2

Description

Control group: Topical use of 25 µL of a placebo cream.

Category

Treatment - 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.

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

Nova pharmed chemia

Full name of responsible person

Razie Rezaee

Street address

No. 1, Sepehr Alley, Shahidi St., Jahan Koudak Crossroads, Vanak Square

City

Tehran

Province

Tehran

Postal code

1518716414

Phone

+98 21 5475 1000

Email

rominarezaee@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Nova pharmed chemia

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

Street address

No. 415, Shahid Naderi (Soheil) Street, Taleqani Avenue

City

Tehran

Province

Tehran

Postal code

1416613675

Phone

+98 21 8897 2220

Email

drtaraneh@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) Street, Taleqani Avenue

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

Dermatology

Street address

No. 415, Shahid Naderi (Soheil) Street, Taleqani Avenue

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

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