

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Comparison study of effect of three types of moisturizers on function skin barrier in healthy volunteers

Protocol summary

Study aim

Evaluation of the effect of 4 types of moisturizer product (Humectant, moisturizing, hydrating and ceramide) on the skin barrier function

Design

It is an interventional study as a randomized double blinded, intra subject clinical study. 25 healthy adult volunteers will participate enrolled in the study after signing informed consent. Simple randomization is performed to assign each treatment site in subjects, using blind cards.

Settings and conduct

The study will be conducted in Center for Research & Training in Skin Diseases and Leprosy. Participants will receive 25 µL of each moisturizer product, twice a day for 2 weeks on assigned area on right and left forearms. The assessments of skin biophysical parameters (skin hydration, trans epidermal water loss and skin elasticity) will be performed before intervention and 1, 4, 24 and 2 weeks later as well as one week after stop taking it. Participant blindness performed packing products in similar containers with different numeric code. For assessor blinding, the randomization list is given to a third person. Formulation to the participants assigned after receiving the randomization code by researcher.

Participants/Inclusion and exclusion criteria

Inclusion criteria: general health, signing informed consent, clinically diagnosed dry skin. Exclusion criteria: active smoker, Presenting an infection or active skin lesion on treatment site, cutaneous or systemic diseases lead to dry skin, pregnancy or breast feeding

Intervention groups

Using 4 types of moisturizer product (occlusive, humectant, hydrating and ceramide) twice a day for 2 weeks.

Main outcome variables

Change of stratum corneum hydration after using four types of moisturizers

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190210042676N2**

Registration date: **2019-06-16, 1398/03/26**

Registration timing: **registered_while_recruiting**

Last update: **2019-06-16, 1398/03/26**

Update count: **0**

Registration date

2019-06-16, 1398/03/26

Registrant information

Name

Aniseh Samadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-15, 1398/01/26

Expected recruitment end date

2019-07-17, 1398/04/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison study of effect of three types of moisturizers on function skin barrier in healthy volunteers

Public title

Comparison study of the effect of moisturizers

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

General health Be willing to comply with all sessions of the treatment schedule and procedures Clinically diagnosed dry skin

Exclusion criteria:

active smoker Presenting an infection or active skin lesion of treatment site Cutaneous or systemic diseases or any skin condition caused dry skin Currently pregnant or lactating

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **25**

More than 1 sample in each individual

Number of samples in each individual: **4**

Two determined regions from right and left forearm area are assigned to use one of the humectant and hydrating formulations randomly .The lower right forearm region is constantly considered as a control point. After that, participants will be in a washout for two weeks.They continue not to use topical compounds then repeat the same process described for ceramide and occlusive formulations.

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is done by simple randomization using a blind card.In this way, the name of the formulation is written on the same card. A card is selected randomly for each region.

Blinding (investigator's opinion)

Double blinded

Blinding description

For participant blindness, products of all groups are packed in similar boxes with different numeric code. In case of assessor blinding, the randomization list is given to a third person. Assignment of the formulation to the treatment sites of participants is made after receiving the code of randomization by researcher.

Placebo

Not used

Assignment

Parallel

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.

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Province

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1417653761

Approval date

2019-02-23, 1397/12/04

Ethics committee reference number

IR.TUMS.VCR.REC.1397.1000

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

Skin moisturizing

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Comparison change in stratum corneum hydration after using four types of moisturizers

Timepoint

Before intervention and 1 and 4 hours, 24 h, 2weeks after using and one week after not using

Method of measurement

Corneometry

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

Skin elasticity

Timepoint

Before intervention and 1 and 4 hours, 24 h, 2weeks after using and one week after not using

Method of measurement

Cutometry

2

Description

Trance Epidermal Water Loss

Timepoint

Before intervention and 1 and 4 hours, 24 h, 2weeks after using and one week after not using

Method of measurement

Tewameter

3

Description

Skin sebum

Timepoint

Before intervention and 1 and 4 hours, 24 h, 2weeks after using and one week after not using

Method of measurement

Sebumeter

Intervention groups

1

Description

Using 4 moisturizer groups (occlusive, Humectant, hydrating and ceramide) day for 2 weeks

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

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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

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Sahraiiian

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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

Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Aniseh Samadi

Position

Supervisor of clinical study unit

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

Contact

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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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Position

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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

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available