

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

Evaluation the effect of 24 -hour moisturizers on barrier function in healthy volunteers.

Protocol summary

Study aim

Evaluation of the effect of 2 super moisturizer formulations on the skin barrier function

Design

It is a interventional study as a randomized double blinded, intra subject clinical study. 20 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 2 types of super moisturizer products (Eucerin and Prime) as well as cream base formulation , once 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, skin elasticity and skin friction) will be performed before intervention and 1, 4, 24 and 2 weeks later. After 2 weeks skin biopsy will be performed from test and control site and Aquaporin 3 expression will be assessed using real time PCR. 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 2 types of super moisturizer products (Eucerin Moist 24 and Prime Moist 24) as well as cream base formulation once a day for 2 weeks.

Main outcome variables

Change of stratum corneum hydration 24 hours after using 3 formulations

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190210042676N4**

Registration date: **2019-09-06, 1398/06/15**

Registration timing: **prospective**

Last update: **2019-09-06, 1398/06/15**

Update count: **0**

Registration date

2019-09-06, 1398/06/15

Registrant information

Name

Aniseh Samadi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2019-11-22, 1398/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of 24 -hour moisturizers on barrier function in healthy volunteers.

Public title

Evaluation the effect of 24 -hour moisturizers

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Male or female aged 18-60 years The presence of skin dryness Voluntary participation and signing written informed consent

Exclusion criteria:

Active skin diseases Active smoking Pregnancy or breastfeeding Using systemic corticosteroid in the past 30 days Use of any topical drugs in the past 7 days Scar, wound or any condition on the inner forearms that could interfere with a clear-cut assessment of the skin

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**

More than 1 sample in each individual

Number of samples in each individual: **3**

Two determined regions from right and left forearm area are assigned to use one 24 hours formulation A and 24 hours formulation B randomly .The lower right forearm region is constantly considered as a control point and using cream base formulation.

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**

National institute for medical research development

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No.21-Besat Street- West Fatemi Avenue

City

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Province

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Postal code

۱۴۱۹۶۹۳۱۱۱

Approval date

2019-01-21, 1397/11/01

Ethics committee reference number

IR.NIMAD.REC.1397.405

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 cream base formulation

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**

aquaporin 3 (AQP3) mRNA level

Timepoint

After two weeks application

Method of measurement

Real time PCR

2**Description**

Trans 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 elasticity

Timepoint

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

Method of measurement

Cutometry

Intervention groups

1

Description

Intervention group: Typical use of 25 µL of 2 types of
super moisturizers: Prime 24 hours moisturizer
(containing Imperata Cylindrica as active ingredient) and
Eucerin Aquaporin active moisturizer (containing Gluco
Glycerol as active ingredient) once a day for 2 weeks

Category

Treatment - Other

2

Description

Control group: Using 25 µL of cream base formulation
once a 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

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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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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

No - There is not 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