Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 a interventional study as a randomized double blinded, intra subject clinical study. 25 healthy adult volunteers will participate enrolled in the study after signing infirmed 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. Participate 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 inform 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

+98 21 8897 2220

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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.
City
Tehran
Province
Tehran
Postal code
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
Cutometery

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 Sahraiian
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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
Superviser 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

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

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Person responsible for updating data

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Position
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Latest degree
Medical doctor

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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