

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

16 Sep 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 formulation

#### 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)

##### Phone

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##### Email address

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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 developement

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No.21-Besat Street- West Fatemi Avenue

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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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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Mohammad Ali Sahraian

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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

**Name of organization / entity**  
Tehran University of Medical Sciences  
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## Person responsible for updating data

### Contact

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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