

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 2026

### Evaluation the effect of 3 compound formulation of moisturizers compare with similar commercial products

#### Protocol summary

##### Study aim

Evaluation the effect of 3 compound formulation of moisturizers compare with similar commercial products

##### Design

It is a interventional study as a randomized double blinded, intra subject clinical study. 30 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

Intervention group: Using 3 formulated moisturizers twice a day for 2 weeks Control group: Using 3 commercial formulated moisturizers twice a day for 2 weeks

##### Main outcome variables

Comparison the change in stratum corneum hydration after using 3 types of moisturizers and similar commercial formulation

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190210042676N9**

Registration date: **2020-05-31, 1399/03/11**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-05-31, 1399/03/11**

Update count: **0**

##### Registration date

2020-05-31, 1399/03/11

##### Registrant information

##### Name

Aniseh Samadi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8897 2220

##### Email address

a\_samadi@razi.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-04-20, 1399/02/01

##### Expected recruitment end date

2020-06-21, 1399/04/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation the effect of 3 compound formulation of moisturizers compare with similar commercial products

**Public title**

Evaluation the effect of 3 compound formulation of moisturizers

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Male or female aged 18-60 years The presence of skin dryness base on Corneometry 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 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**

3

**Groups that have been masked**

- Participant
- Investigator

**Sample size**

Target sample size: **30**

**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**

2019-12-17, 1398/09/26

**Ethics committee reference number**

IR.TUMS.VCR.REC.1398.710

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

Skin moisturizing

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

Comparison the change in stratum corneum hydration after using 3 types of moisturizers and similar commercial 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**

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

**2****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: Using 3 formulated moisturizers twice a day for 2 weeks

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Using 3 commercial formulated moisturizers twice a day for 2 weeks

#### Category

Treatment - Drugs

## 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

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##### Postal code

1416613675

##### Phone

+98 21 8897 0658

##### Email

dermalab@tums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tehran University of Medical Sciences

##### Full name of responsible person

Mohammad Ali Sahraiiian

##### Street address

6th floor, Ghods St., Keshavarz Blv.

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##### Postal code

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##### Phone

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##### Email

research@ut.ac.ir

#### 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

Manger of clinical study unit

##### Latest degree

Medical doctor

##### Other areas of specialty/work

General Practitioner

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aniseh\_samadi@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

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## 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**  
Clinical Research  
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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

Not applicable

### 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