

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 2026

### Evaluating effectiveness of the moisturizing cream produced by Behpad Teb Company using skin biometric methods.

#### Protocol summary

##### Study aim

Evaluating effectiveness of the moisturizing cream produced by Behpad Teb Company using skin biometric methods.

##### Design

Single group, phase 2, before -after clinical study. sample size is 19. The study is not randomized.

##### Settings and conduct

The study will be performed in Center for the Study and Research of Diseases of the Skin and Leprosy, 20 Cases of Clinically diagnosed dry skin will be selected and enrolled in the study after signing consent form. Volunteers will be taught to use moisturizing cream produced by Behpad Teb Company for 2 weeks, twice in a day. Before intervention ,1 hours and 2 weeks after using changing in stratum corneum hydration, skin elasticity and Trance Epidermal Water Loss (TEWL) will be measured. This study is not blinded.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Clinically diagnosed dry skin, general health, be willing to comply with all sessions of the treatment schedule and procedures. exclusion criteria: active smokers, 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.

##### Intervention groups

Topical use of 25 µL of moisturizing cream produced by Behpad Teb Company on assigned area of the right forearm for 2 weeks twice a day.

##### Main outcome variables

Comparison changes in stratum corneum hydration.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190210042676N28**

Registration date: **2023-01-17, 1401/10/27**

Registration timing: **prospective**

Last update: **2023-01-17, 1401/10/27**

Update count: **0**

##### Registration date

2023-01-17, 1401/10/27

##### 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

2023-02-20, 1401/12/01

##### Expected recruitment end date

2023-08-23, 1402/06/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluating effectiveness of the moisturizing cream produced by Behpad Teb Company using skin biometric methods.

##### Public title

Evaluating effectiveness of the moisturizing cream

produced by Behpad Teb Company

#### **Purpose**

Treatment

#### **Inclusion/Exclusion criteria**

##### **Inclusion criteria:**

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

##### **Exclusion criteria:**

active smokers 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

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **20**

#### **Randomization (investigator's opinion)**

N/A

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Not blinded

#### **Blinding description**

#### **Placebo**

Not used

#### **Assignment**

Single

#### **Other design features**

### **Secondary Ids**

empty

### **Ethics committees**

#### **1**

##### **Ethics committee**

###### **Name of ethics committee**

Ethics committee of The Institute of Pharmaceutical Sciences of Tehran University of Medical Science

###### **Street address**

Unit 1-219, 2nd floor, The Institute of Pharmaceutical Sciences, Faculty of Pharmacy, 16 Azar Avenue

###### **City**

Tehran

###### **Province**

Tehran

###### **Postal code**

1417613151

##### **Approval date**

2023-01-03, 1401/10/13

##### **Ethics committee reference number**

IR.TUMS.TIPS.REC.1401.096

### **Health conditions studied**

#### **1**

##### **Description of health condition studied**

Skin dryness

##### **ICD-10 code**

##### **ICD-10 code description**

### **Primary outcomes**

#### **1**

##### **Description**

Comparison changes in stratum corneum hydration.

##### **Timepoint**

Before intervention, 1 hours and 2weeks after using.

##### **Method of measurement**

Corneometry

### **Secondary outcomes**

#### **1**

##### **Description**

Skin elasticity

##### **Timepoint**

Before intervention, 1 hours and 2weeks after using.

##### **Method of measurement**

Cutometry

#### **2**

##### **Description**

Trance Epidermal Water Loss

##### **Timepoint**

Before intervention, 1 hours and 2weeks after using.

##### **Method of measurement**

Tewameter

### **Intervention groups**

#### **1**

##### **Description**

Intervention group: Topical use of 25 µL of moisturizing cream produced by Behpad Teb Company on assigned area of the right forearm for 2 weeks twice a day.

##### **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

**Street address**

No. 415, Shahid Naderi (Soheil) St., Taleqani Ave.

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1416613675

**Phone**

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**Email**

dermalab@tums.ac.ir

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

Iranian Behpad Teb Company

**Full name of responsible person**

Reza Payandeh

**Street address**

2nd Floor, No. 37, West Nusrat Street, North Kargar Street

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**Province**

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**Postal code**

1418863983

**Phone**

+98 21 6642 6890

**Email**

behpadteb.drug@gmail.com

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Iranian Behpad Teb Company

**Proportion provided by this source**

100

**Public or private sector**

Private

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

Persons

**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**

Ph.D.

**Other areas of specialty/work**

Dermatology

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Azin Ayatollahi

**Position**

Dermatologist

**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**

Dermatology

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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**  
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