

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

Efficacy and safety evaluation of the cream including Citystem extract derived from Marrubium vulgare plant and Phytessence extract derived from Phytessence peach flower on reducing skin damage caused by air pollution

Protocol summary

Study aim

Efficacy and safety evaluation of the cream including Citystem extract derived from Marrubium vulgare plant and Phytessence extract derived from Phytessence peach flower on reducing skin damage caused by air pollution

Design

Clinical trial is two parallel group, two blinded side, phase 3 in 26 people. Balance Blocked Randomization in size 4. The randomization sequence is prepared by a statistician. Based on the specified randomized sequence, it places the participant into treatment groups and provides them with the drugs that have been tagged with the specific code of each participant.

Settings and conduct

The study is a parallel evaluation of efficacy and safety of a cream including Citystem extract derived from Marrubium vulgare plant and Phytessence extract derived from Phytessence peach flower on reducing skin damage caused by air pollution on healthy volunteer in Center For Research and Training in skin Diseases and Leprosy. The study is double blinded and Center researchers and participants will be unaware of the study sequence.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Signing the informed consent form and agree to regularly attend follow-up courses, 18 -50 years old men and women, Exposure to the outside air (at least one hour in a day) Exclusion criteria: People with any kind of skin disease, Suffering from a chronic disease affecting the skin condition (diabetes, thyroid diseases,...), Smoking, Pregnancy or lactation

Intervention groups

Intervention group: Using twice a day (morning and night) the cream containing Citystem extract derived from Marrubium vulgare plant and Phytessence extract

derived from Phytessence peach flower plant protects the skin for 8 weeks Control group: Using a placebo cream twice a day with the same smell, color and shape as the cream of the intervention group for 4 weeks

Main outcome variables

Trance epidermal water lost (TEWL)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161207031288N14**

Registration date: **2022-11-26, 1401/09/05**

Registration timing: **registered_while_recruiting**

Last update: **2022-11-26, 1401/09/05**

Update count: **0**

Registration date

2022-11-26, 1401/09/05

Registrant information

Name

Saman Ahmad Nasrollahi

Name of organization / entity

Center for Research and Training in Skin Diseases and Leprosy Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8896 8190

Email address

snasrollahi@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-21, 1401/08/30

Expected recruitment end date

2023-05-20, 1402/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy and safety evaluation of the cream including Citystem extract derived from Marrubium vulgare plant and Phytessence extract derived from Phytessence peach flower on reducing skin damage caused by air pollution

Public title

Efficacy and safety evaluation of the cream including Citystem extract and Phytessence extract on reducing skin damage caused by air pollution

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Signing the informed consent form and agree to regularly attend follow-up courses 18 -50 years old men and women Exposure to the outside air (at least one hour in a day)

Exclusion criteria:

People with any kind of skin disease Suffering from a chronic disease affecting the skin condition (diabetes, thyroid diseases,...) Smoking Pregnancy or lactation

AgeFrom **18 years** old to **50 years** old**Gender**

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample sizeTarget sample size: **26****Randomization (investigator's opinion)**

Randomized

Randomization description

Balance Blocked Randomization in size 4. An online site (<https://www.sealedenvelope.com>) will be used to generate a randomized list of study groups. According to the random block method and considering the four blocks, 7 blocks will be produced for 26 patients. Finally, 2 samples are removed to reach 26 patients.

Blinding (investigator's opinion)

Double blinded

Blinding description

Center researchers and participants will be unaware of the study sequence. After confirming new participant to the study and registering the participant code, the study coordinator who is located on the participant recruitment

site. Based on the specified randomized sequence and places the participant into treatment groups. and provides them with the drugs that have been tagged with the specific code of each participant.

Placebo

Used

Assignment

Parallel

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

2021-11-29, 1400/09/08

Ethics committee reference number

IR.TUMS.TIPS.REC.1400.175

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

Skin damage caused by air pollution

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

Trance epidermal water lost (TEWL)

Timepoint

Before the study, 4 and 8 weeks after the intervention

Method of measurement

MPA 580(Multi Probe Adaptor) device

Secondary outcomes**1****Description**

Skin PH
Timepoint
Before the study, 4 and 8 weeks after the intervention
Method of measurement
MPA 580(Multi Probe Adaptor) device

2

Description
Skin erythema
Timepoint
Before the study, 4 and 8 weeks after the intervention
Method of measurement
MPA 580(Multi Probe Adaptor) device

Intervention groups

1

Description
Intervention group:Using twice a day (morning and night) the cream containing Citystem extract derived from Marrubium vulgare plant and Phytessence extract derived from Phytessence peach flower plant protects the skin for 8 weeks
Category
Treatment - Drugs

2

Description
Control group:Using a placebo cream twice a day with the same smell, color and shape as the cream of the intervention group for 4 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Center for research and training in skin diseases and leprosy, Tehran University of Medical Sciences
Full name of responsible person
Aniseh Samadi
Street address
415, Taleghani Avenue.
City
Tehran
Province
Tehran
Postal code
1416613675
Phone
+98 21 8897 2220
Email
dermalab@tums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Ali Akbar Fotouhi
Street address
6th floor,Ghods St.,Keshavarz Blv.
City
Tehran
Province
Tehran
Postal code
1417653761
Phone
+98 21 8163 3685
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
Saman Ahmad Nasrollahi
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
415, Taleghani St.,Naderi St.
City
Tehran
Province
Tehran
Postal code
1416613675
Phone

+98 21 8897 2220

Email

samannasrol@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Alireza Firooz

Position

Proffesor of Dermatology

Latest degree

Specialist

Other areas of specialty/work

Dermatology

Street address

415, Taleghani St.,Naderi St.

City

Tehran

Province

Tehran

Postal code

1416613675

Phone

+98 21 8897 2220

Email

firozali@tums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Maryam Ahmadi

Position

Researcher

Latest degree

Master

Other areas of specialty/work

Dermatology

Street address

No. 415, Shahid Naderi Street, Taleqani Avnue

City

Tehran

Province

Tehran

Postal code

1416613675

Phone

+98 21 8897 2220

Email

dermalab@tums.ac.ir

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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Not applicable