

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

23 Jun 2026

### consideration of clinical safety and efficacy of topical formulation of polyphenolic extract of punica granatum on patients with mild to moderate forms of melasma

#### Protocol summary

##### Study aim

Assessment of safety and efficacy of a cream containing pomegranate peel extract on patients with mild to moderate melasma

##### Design

Clinical trial without control group, non-blinded and non-randomised in phase 2 on 20 patients.

##### Settings and conduct

The study would be done as before-after trial with prescription of a cream containing pomegranate peel extract on the skin of patients with mild to moderate melasma in Center for Research and Training in Skin Diseases And Leprosy

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Mild to moderate melasma with minimum grade of Melasma Area and Severity Index=1; Age range 18-50; signing consent form. Exclusion criteria: Pregnancy or lactation; Use of systemic corticosteroid or isotretinoin; using any light sensitizing medicine; Active skin disease at test area; Use of topical lightening products like beta hydroxy acid, alpha hydroxy acid and products containing retinoid; Documented allergies to components of cream; History of laser treatment or dermabrasion or deep facial peels

##### Intervention groups

Intervention group involves patients receiving cream containing pomegranate peel extract, who apply the cream on melasma areas, two times a day (morning and night).

##### Main outcome variables

Modified melasma severity index

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20161207031288N6**

Registration date: **2020-10-12, 1399/07/21**

Registration timing: **prospective**

Last update: **2020-10-12, 1399/07/21**

Update count: **0**

##### Registration date

2020-10-12, 1399/07/21

##### 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

2020-10-22, 1399/08/01

##### Expected recruitment end date

2021-01-20, 1399/11/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

consideration of clinical safety and efficacy of topical

formulation of polyphenolic extract of punica granatum on patients with mild to moderate forms of melasma

#### Public title

Assessment of pomegranate whitening cream on melasma

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Mild to moderate melasma with minimum grade of Melasma area and severity index = 1 Age range 18-50 Signing consent form, voluntarily and knowingly

##### Exclusion criteria:

Pregnancy or lactation Using oral corticosteroids or isotretinoin within 28 days prior to the study Any active skin disease at test area including rosacea, eczema, atrophy, acne Using any light sensitizing medicine within 3 months prior to the study Use of topical lightening products like alpha hydroxy acid, beta hydroxy acid, and retinoid component within 21 days prior to the study Documented allergy to components of the cream History of laser treatment or dermabrasion or deep facial peeling within the past 3 months prior to the study Using contraceptive or hormonal medicines

#### Age

From **18 years** old to **50 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 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

2019-12-31, 1398/10/10

#### Ethics committee reference number

IR.TUMS.VCR.REC.1398.763

## Health conditions studied

### 1

#### Description of health condition studied

Melasma

#### ICD-10 code

L81.1

#### ICD-10 code description

Chloasma

## Primary outcomes

### 1

#### Description

modified melasma severity index

#### Timepoint

Before intervention, 4 weeks later, 8 weeks after intervention

#### Method of measurement

Modified Melasma Area and Severity Index

## Secondary outcomes

### 1

#### Description

skin pH

#### Timepoint

At the beginning (before start of the intervention) and 4 and 8 weeks after start of the intervention

#### Method of measurement

Cutometer MPA 580

### 2

#### Description

Skin sebum

#### Timepoint

At the beginning (before start of the intervention) and 4 and 8 weeks after start of the intervention

#### Method of measurement

Cutometer MPA 580

### 3

#### Description

Skin melanin and erythem

#### Timepoint

At the beginning (before start of the intervention) and 4 and 8 weeks after start of the intervention

**Method of measurement**

Cutometer MPA 580

**4**

**Description**

Transepidermal water loss

**Timepoint**

At the beginning (before start of the intervention) and 4 and 8 weeks after start of the intervention

**Method of measurement**

Cutometer MPA 580

**5**

**Description**

Size and value of skin spot

**Timepoint**

At the beginning (before start of the intervention) and 4 and 8 weeks after start of the intervention

**Method of measurement**

Visio face device

**Intervention groups**

**1**

**Description**

Intervention group: Approving the whitening cream on patient with mild to moderate melasma (single arm study)

**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**

Saman Ahmad Nasrollahi

**Street address**

415, Taleghani Ave., Tehran, Iran

**City**

Tehran

**Province**

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**Postal code**

1416613675

**Phone**

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**Email**

samannasrol@gmail.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Mohamad Ali Sahraeian

**Street address**

6th floor, Vice chancellor in research affairs, Qods Ave., Keshavarz Blvd.

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+98 21 8163 3685

**Email**

vcr@tums.ac.ir

**Web page address**

<https://vcr.tums.ac.ir/>

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

No

**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**

Center For Research And Training In Skin Diseases And Leprosy

**Full name of responsible person**

Saman Ahmad Nasrollahi

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Pharmacy

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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  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Dermatology  
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No. 415, Taleqni Ave., Tehran, Iran  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Faezeh Rakhshan  
**Position**  
Student  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Medical Pharmacy  
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No.1, Poursina street, Ghods street, Keshavarz Blvd,  
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**Phone**  
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**Email**  
faezerakhshan@yahoo.com

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

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

### Informed Consent Form

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

### Clinical Study Report

Yes - There is 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

### Title and more details about the data/document

Whole data is publishable after making patients identity unrecognisable

### When the data will become available and for how long

Beginning of access to data would be six months after publishing of data

### To whom data/document is available

Academic researchers

### Under which criteria data/document could be used

Any sort of application of data is allowed, except using for making medicine based on the research

### From where data/document is obtainable

For accessing data refer to Dr. Mahdi Vazirian. Address: Faculty of Pharmacy, In front of Nosrat Ave., 16th Azar Ave., Keshavarz Blvd., Tehran, Iran.

### What processes are involved for a request to access data/document

Sending an E. mail request (mehdivazirian@gmail.com) or in-person referring to mentioned address. Data would be presentable within one week after request.

### Comments