

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

Tehran

Postal code

1416613675

Phone

+98 21 8897 2220

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.

City

Tehran

Province

Tehran

Postal code

1416613675

Phone

+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

Street address

415 Taleqani Ave., Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1416613675

Phone
+98 21 8896 0880
Fax
+98 21 8896 3804
Email
snasrollahi@tums.ac.ir

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
Street address
No. 415, Taleqni Ave., Tehran, Iran
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
Faezeh Rakhshan
Position
Student
Latest degree
Master
Other areas of specialty/work
Medical Pharmacy
Street address
No.1, Poursina street, Ghods street, Keshavarz Blvd,
Tehran, Iran

City
Tehran
Province
Tehran
Postal code
1417653911
Phone
+98 21 8897 7921
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