Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 watre 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 Laprosy

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 fron ot 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