

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Efficacy and safety assessment of a formulated topical cream containing Ginger for treatment of mild to moderate melasma

Protocol summary

Study aim

Efficacy and safety assessment of a formulated topical cream containing Ginger for treatment of mild to moderate melasma

Design

parallel group, phase 3, treatment-control clinical study. sample size is 30. Randomization is done by random block method.

Settings and conduct

The study will be performed in Center for the Study and Research of Diseases of the Skin and Leprosy. 30 healthy volunteers will be selected and enrolled in the study after signing consent form. Individuals enter one of two intervention groups based on the randomization list (topical cream containing Ginger or 2% hydroquinone cream). Volunteers are taught to use the product assigned to the group for 12 weeks twice a day on their spots. At the end of weeks 6 and 12 as well as 3 months later, the severity of skin spots measured by mMASI.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Case of mild to moderate melasma (MGSC=1& 2), general health, signing the consent form for participation in the study. Exclusion criteria: Documented allergies to components of cream, Use of topical lightening products like AHA, BHA and retinoid component within, 21 days prior to the study, Active skin disease at test area: rosacea, atrophy, acne and eczema, Pregnancy or lactating, Use of systemic corticosteroid, isotretinoin within 28 days prior to the study, History of laser treatment or dermabrasion or deep facial peels within the past 3 months

Intervention groups

Apply the topical cream containing Ginger and 2% hydroquinone cream as a control, for 12 weeks twice a day on the facial spots

Main outcome variables

modified melasma severity index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190210042676N8**

Registration date: **2020-05-31, 1399/03/11**

Registration timing: **prospective**

Last update: **2020-05-31, 1399/03/11**

Update count: **0**

Registration date

2020-05-31, 1399/03/11

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

2020-07-05, 1399/04/15

Expected recruitment end date

2021-01-04, 1399/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy and safety assessment of a formulated topical cream containing Ginger for treatment of mild to moderate melasma	
Public title	Effect of anti-stain cream containing Ginger melasma
Purpose	Treatment
Inclusion/Exclusion criteria	Inclusion criteria: Cases of mild to moderate melasma (MGSC=1& 2) General health Signing the consent form for participation in the study Exclusion criteria: Documented allergies to components of cream Use of topical lightening products like AHA ,BHA and retinoid component within 21 days prior to the study Active skin disease at test area: rosacea, atrophy, acne and eczema Pregnancy or lactating Use of systemic corticosteroid and isotretinoin within 28 days prior to the study History of laser treatment or dermabrasion or deep facialpeels within the past 3 months
Age	From 18 years old to 50 years old
Gender	Both
Phase	2-3
Groups that have been masked	Investigator
Sample size	Target sample size: 28
Randomization (investigator's opinion)	Randomized
Randomization description	volunteers enter one of two intervention groups based on the randomization list (topical cream containing Ginger or 2% hydroquinone cream).Randomization is done by random block method. According to the random block method and considering the four blocks, 7 blocks will be produced for 28patients.
Blinding (investigator's opinion)	Single blinded
Blinding description	The assessor doesn't know that each volunteer uses the control or studying cream
Placebo	Not used
Assignment	Parallel
Other design features	
Secondary Ids	empty
Ethics committees	
<u>1</u>	
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 2020-04-07, 1399/01/19 Ethics committee reference number IR.TUMS.VCR.REC.1399.161
Health conditions studied	
<u>1</u>	
Description of health condition studied	melasma
ICD-10 code	L81.4
ICD-10 code description	Other melanin hyperpigmentation
Primary outcomes	
<u>1</u>	
Description	Modified melasma severity index
Timepoint	Before intervention, 6 and 12weeks after intervention and 3 months after stop using
Method of measurement	mMASI
Secondary outcomes	
<u>1</u>	
Description	Size and amount of skin spots
Timepoint	Before intervention, 6 and 12 weeks after using and 3 months after stop using
Method of measurement	Visio face
<u>2</u>	
Description	Melanin content changes
Timepoint	Before intervention,6 and 12 weeks after using and 3 months after stop using
Method of measurement	mexameter

Intervention groups

1

Description

Intervention group: Approving a formulated topical cream containing Ginger on patient with mild to moderate melasma

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

Aniseh Samadi

Street address

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

City

Tehran

Province

Tehran

Postal code

1416613675

Phone

+98 21 8897 0658

Email

dermalab@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sina Trading Company

Full name of responsible person

mehdi goudarzi

Street address

No. 12, Unit 12, Zayandehrud Alley, North Shiraz St., Mulla Sadra St.

City

چابهار

Province

Sistan-va-Balouchestan

Postal code

1991613916

Phone

+98 21 8860 0707

Email

mehdi.goudarzi@sinatco.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Sina Trading 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

Anise Samadi

Position

Supervisor of clinical study unit

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

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

City

Tehran

Province

Tehran

Postal code

1416613675

Phone

+98 21 8896 0880

Email

aniseh_samadi@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Alireza Firooz

Position

Professor of dermatology

Latest degree

Specialist

Other areas of specialty/work

Dermatology

Street address

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

City

Tehran

Province

Tehran

Postal code

1416613675

Phone

+98 21 8897 7921

Email

firozali@sina.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

Research Expert

Latest degree

Master

Other areas of specialty/work

مطالعات بالینی

Street address

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

City

Tehran

Province

Tehran

Postal code

1416613675

Phone

+98 21 8897 0658

Email

ahmadi.maryam648@gmail.com

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