

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Sep 2026

Evaluation of tolerability and efficacy of Melatrance lightening cream for the treatment of mild to moderate melasma

Protocol summary

Study aim

Evaluation of tolerability and efficacy of Melatrance lightening cream for the treatment of mild to moderate melasma

Design

Single group, phase 2, before -after clinical study. sample size is 19. The study is not randomized.

Settings and conduct

The study will be performed in Center for the Study and Research of Diseases of the Skin and Leprosy, 20 Cases of mild to moderate melasma will be selected and enrolled in the study after signing consent form. Volunteers will be taught to use Melatrance lightening cream for 12 weeks, twice in a day. Before intervention and 6 and 12 weeks after using changing in modified melasma severity index (mMASI), skin melanin content, size and amount of skin spots will be measured. This study is not blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 18 - 50 years old men and women, 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, Pregnancy or lactating

Intervention groups

Using Melatrance lightening cream (Contains Tranexamic acid, Carica papaya, Psidium guajava, saxifragaceae and Pisum sativum) produced by Knowledge-based company of Janus on patient with mild to moderate melasma twice in a day for 12 weeks.

Main outcome variables

modified melasma severity index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190210042676N25**

Registration date: **2022-07-07, 1401/04/16**

Registration timing: **prospective**

Last update: **2022-07-07, 1401/04/16**

Update count: **0**

Registration date

2022-07-07, 1401/04/16

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

2022-07-23, 1401/05/01

Expected recruitment end date

2023-04-21, 1402/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of tolerability and efficacy of Melatrance lightening cream for the treatment of mild to moderate melasma

Public title

Evaluation of tolerability and efficacy of Melatrance lightening cream for the treatment of melasma

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

18 - 50 years old men and women 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 Pregnancy or lactating

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 in research of medical school-
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

2022-06-21, 1401/03/31

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1401.233

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, 6 weeks later and 12 weeks after
intervention

Method of measurement

Using mMASI index

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

Skin melanin content changes

Timepoint

Before intervention, 6 and 12 weeks after using

Method of measurement

mexameter

2**Description**

Size and amount of skin spots

Timepoint

Before intervention, 6 and 12 weeks after using

Method of measurement

Visio face

Intervention groups**1****Description**

Intervention group: Using Melatrance lightening
cream(Contains Tranexamic acid, Carica papaya, Psidium
guajava, saxifragaceae and Pisum sativum)produced by
Knowledge-based company of Janus on patient with mild
to moderate melasma twice in a day for 12 weeks.

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) Street, Taleqani Avenue

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

Knowledge-based company of Janus

Full name of responsible person

Saman Ahmad Nasrollahi

Street address

No. 415, Shahid Naderi St., Taleqani Ave.

City

Tehran

Province

Tehran

Postal code

1416613675

Phone

+98 21 8896 2981

Email

headoffice@januspharma.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Knowledge-based company of Janus

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

Aniseh Samadi

Position

Manger of clinical study unit

Latest degree

Ph.D.

Other areas of specialty/work

Dermatology

Street address

No. 415, Shahid Naderi (Soheil) Street, Taleqani Avenue.

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

Azin Ayatollahi

Position

Dermatologist

Latest degree

Specialist

Other areas of specialty/work

Dermatology

Street address

No. 415, Shahid Naderi (Soheil) Street, Taleqani Avenue

City

Tehran

Province

Tehran

Postal code

1416613675

Phone

+98 21 8897 7921

Email

azinay@gmail.com

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

Dermatology

Street address

No. 415, Shahid Naderi (Soheil) Street, Taleqani Avenue

City

Tehran

Province

Tehran

Postal code

1416613675

Phone

+98 21 8897 7921

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