Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

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

Protocol summary

Study aim
Evaluaion 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
he 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
Evaluaion of tolerability and efficacy of Melatrance lightening cream for the treatment of mild to moderate melasma

Public title
Evaluaion 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