Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of safety and efficacy of Nanostructured lipid carrier(NLC) nanoparticles containing hydroquinone, tretinoin, and fluocinolone compared with conventional formulation in the treatment of melasma

Protocol summary

Study aim

Evaluation the effectiveness of cream containing hydroquinone, tretinoin and fluocinolone nanoparticles and its comparison with the normal form of the cream

Design

Clinical trial, one parallel group, two blinded side, phase 2 in 20 people

Settings and conduct

The study is a parallel evaluation of Nanostructured lipid carrier(NLC) nanoparticles containing hydroquinone, tretinoin, and fluocinolone compared with conventional formulation in the treatment of melasma in Center For Research and Training in skin Diseases and Leprosy

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women or men 18 to 50 years old, patients with almost symmetrical melasma on both sides of the face mild to moderate (at least grade 2 MGSC), no local and systemic treatment for melasma during the last 4 weeks, Appropriate health status, no change in life style during the study, Exclusion criteria: Pregnant or those who intend to become pregnant during the study, individuals with known allergies to any of the components of cream, history of topical use of any of corticosteroids, retinoid compounds, Chemical peels, compounds AHA and BHA in the last 21 days, History of systemic use of corticosteroids, tretinoin compounds, interferon types in the last 28 days, patients with rosacea acne, skin atrophy, acne and eczema, history of using drugs that increase photosensitivity in past 3 months, people who have had laser or microdermabrasion of the skin in the last 3 months, unsuitable to volunteer for the study if their doctor determines for some reasons

Intervention groups

An intervention group consisted of 20 men or women in the age range of 18 to 50 years with almost symmetrical facial melasma who were given two tubes of cream and randomly used each of these tubes on one side of their face. We observe the changes after 4 and 8 weeks.

Main outcome variables

modified melasma severity index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161207031288N13**
Registration date: **2022-07-11, 1401/04/20**
Registration timing: **prospective**

Last update: **2022-07-11, 1401/04/20**
Update count: **0**

Registration date

2022-07-11, 1401/04/20

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

2022-07-23, 1401/05/01

Expected recruitment end date

2023-01-21, 1401/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of safety and efficacy of Nanostructured lipid carrier(NLC) nanoparticles containing hydroquinone, tretinoin, and fluocinolone compared with conventional formulation in the treatment of melasma

Public title

Evaluation of NLC nanoparticles containing hydroquinone, tretinoin, and fluocinolone in the treatment of melasma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

18 - 50 years old men and women Case of approximately symmetrical moderate to severe melasma (melasma global severity score(MGSC)>2) No topical and systemic treatment for melasma during the last 4 weeks Appropriate general health condition No change in life style during the study Signing the consent form of the candidate to participate in the study and the desire to attend regular follow-up courses

Exclusion criteria:

Pregnant people or those who plan to become pregnant during the study People with known allergies to any of the components of the cream History of using each of the mentioned compounds topically in the last 21 days: Corticosteroids, retinoid compounds, chemical peels, alpha hydroxy acid and beta hydroxy acid compounds History of systemic use of each of the mentioned compounds in the last 28 days: corticosteroids, tretinoin compounds, interferon types Patients with rosacea, skin atrophy, acne and eczema History of use of drugs that increase photosensitivity in the last 3 months People who have had laser skin peeling or microdermabrasion in the last 3 months If the doctor of the study determines that the volunteer is not appropriate for this study by some reaons

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **20**

More than 1 sample in each individual

Number of samples in each individual: **2**

According to the random table, each patient is randomly told to apply cream A to the left and cream B to the right of the face or vice versa.

Randomization (investigator's opinion)

Randomized

Randomization description

Each patient with melasma is given two prepared creams in the form of identical packages coded as A and B. The evaluating physician and the patient are both unaware of the ingredients in the two creams. Cream A is said to be rubbed to the left and cream B to the right of the face or vice versa

Blinding (investigator's opinion)

Double blinded

Blinding description

Evaluating physician and the patient are both unaware of the ingredients in the two creams

Placebo

Not used

Assignment

Parallel

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

2021-03-07, 1399/12/17

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1399.1228

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
Using mMASI(modified Melasma Severity Index)

Secondary outcomes

1

Description
skin pH
Timepoint
Before intervention, 4 weeks later, 8 weeks after intervention
Method of measurement
MPA 580

2

Description
Skin sebum
Timepoint
Before intervention, 4 weeks later, 8 weeks after intervention
Method of measurement
MPA 580

3

Description
Skin melanin and erythem
Timepoint
Before intervention, 4 weeks later, 8 weeks after intervention
Method of measurement
MPA 580

4

Description
Trance Epidermal Water Lost (TEWL)
Timepoint
Before intervention, 4 weeks later, 8 weeks after intervention
Method of measurement
MPA 580

5

Description
Size and value of skin spot
Timepoint
Before intervention, 4 weeks later, 8 weeks after intervention
Method of measurement
Visio face

Intervention groups

1

Description
Intervention group: use of Nanostructured lipid carrier(NLC) nanoparticles containing hydroquinone, tretinoin and fluosinolone made in lab, in patients with moderate to severe melasma in one side of patient's face once in a day for 8 weeks
Category
Treatment - Drugs

2

Description
Control group: use of commercial formulations containing hydroquinone, tretinoin and fluosinolone made by Janus pharma company, in patients with moderate to severe melasma on one side of the patient's face once in a day for 8 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
Shaghayegh Afzali
Street address
No. 415, Shahid Naderi Street, Taleqani Avnue
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Phone
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Fax
+98 21 8896 3804
Email
dermalab@sina.tums.ac.ir
Web page address
https://crtsdl.tums.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Akbar Fotoohi
Street address
Tehran University of Medical Sciences, 16 Azar St.,

Enghelab Square
City
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Province
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Postal code
۱۴۱۷۶۱۴۴۱۱
Phone
Email
pharmacy@tums.ac.ir
Web page address
https://pharmacy.tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
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
Tehran University of Medical Sciences
Full name of responsible person
Saman Ahmad Nasrollahi
Position
assistant professor
Latest degree
Specialist
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Alireza firooz
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Proffesor of Dermatology
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Specialist
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Postal code
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Person responsible for updating data

Contact
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Full name of responsible person
Shaghayegh afzali
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student
Latest degree
A Level or less
Other areas of specialty/work
Medical Pharmacy
Street address
Tehranpars, 3rd Square, between Bagheri and Ordibehesht Highways, Shahid Ghazaghi St., Babam Mohammadi St.
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Postal code
1686994631
Phone
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Email
shaghayeghafzali266@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information
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

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable