

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

22 Jul 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 reasons

**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

#### **City**

Tehran

#### **Province**

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#### **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  
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**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  
**Other areas of specialty/work**  
 Medical Pharmacy  
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 samannasrol@gmail.com

## Person responsible for scientific inquiries

**Contact**  
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Tehran University of Medical Sciences  
**Full name of responsible person**  
 Alireza firooz  
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 Proffesor of Dermatology  
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## Person responsible for updating data

**Contact**  
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**Full name of responsible person**  
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 student  
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 A Level or less  
**Other areas of specialty/work**  
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 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