

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Efficacy and safety assessment of Januluma cream for treatment of moderate to severe melasma . A single arm, phase II clinical trial

#### Protocol summary

##### Summary

The aim of this study is to assess the efficacy and safety of Januluma cream for treatment of moderate to severe melasma in Iranian patients. It is a single arm, phase III clinical trial. 20 patients with melasma global severity score >2 recruited in the study. They are not allowed to use systemic corticosteroid and isotretinoin within past 28 days. Eligible subjects will receive Januluma cream once a day for four weeks. All subjects will be asked to return for follow-up 4 and 8 weeks after finishing the treatment. Digital photographs will be taken by VisioFace and subjects will be assessed for the Modified melasma severity index at baseline and follow-up visits. Also, Corneometer, TEWAmeter, Mexameter, Sebumeter, pH meter and ultrasonographic measurements will be determined at baseline and follow-up visits. Subjects will also rate overall satisfaction based on Visual Analogue scale (0-No satisfaction, 10- very much satisfaction) on both follow-up visits. Primary outcome will be change in Modified melasma severity index after 8 weeks.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016121031288N2**  
Registration date: **2017-04-07, 1396/01/18**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-04-07, 1396/01/18

##### 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

Jarfandishan-e Navid-e Salamat (Janus) knowledge-based company

##### Expected recruitment start date

2016-12-20, 1395/09/30

##### Expected recruitment end date

2017-12-20, 1396/09/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Efficacy and safety assessment of Januluma cream for treatment of moderate to severe melasma . A single arm, phase II clinical trial

##### Public title

Effect of whitening cream on melasma

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion : Case of moderate to severe melasma (MGSC>2); age range 18-50 (men or women); signed informed consent voluntarily and knowingly Exclusion :pregnancy or lactation; use of systemic corticosteroid, isotretinoin within 28 days prior to the study; use any light sensitive drug within 3 months prior to the study;

Active skin disease at test area: rosacea, atrophy, acne, eczema; Use of topical lightening products like AHA ,BHA and retinoid component within 21 days prior to the study; Documented allergies to components of Januluma cream: Use of contraceptive or any hormonal drugs: History of laser treatment or dermabrasion or deep facial peels within the past 3 months

#### Age

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

#### Gender

Both

#### Phase

3

#### 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

Pharmaceutical Sciences Branch, Ethic committee of Islamic Azad University

##### Street address

Yakhchal street ,Gholhak, Tehran

##### City

Tehran

##### Postal code

19395-6466

#### Approval date

2016-05-17, 1395/02/28

#### Ethics committee reference number

IR.IAU.PS.REC.1395.13

## 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, one month later, two month after intervention

#### Method of measurement

mMASI

## Secondary outcomes

### 1

#### Description

skin pH

#### Timepoint

before and after 4 and 8 weeks

#### Method of measurement

MPA 580

### 2

#### Description

Skin sebum

#### Timepoint

Before and after 4 and 8 weeks

#### Method of measurement

MPA 580

### 3

#### Description

Skin melanin and erythem

#### Timepoint

before and after 4 and 8 weeks

#### Method of measurement

MPA 580

### 4

#### Description

TEWL

#### Timepoint

before and after 4 and 8 weeks

#### Method of measurement

MPA 580

### 5

#### Description

Size and value of skin spot

#### Timepoint

before and after 4 and 8 weeks

#### Method of measurement

Visioface

## Intervention groups

1

### Description

Approving the Januluma whitening cream on patient with moderate to severe melasma (single arm study )

### 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

#### Street address

#### City

Tehran

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Jarfandishan-e Navid-e Salamat (Janus) knowledge-based company

#### Full name of responsible person

Najva Kashani

#### Street address

No. 415, Taleqni Ave., Tehran, Iran

#### City

Tehran

### Grant name

### Grant code / Reference number

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

Yes

### Title of funding source

Jarfandishan-e Navid-e Salamat (Janus) knowledge-based company

### Proportion provided by this source

100

### Public or private sector

*empty*

### Domestic or foreign origin

*empty*

### Category of foreign source of funding

*empty*

### Country of origin

### Type of organization providing the funding

*empty*

## Person responsible for general inquiries

### Contact

#### Name of organization / entity

Center For Research And Training In Skin Diseases And Leprosy

#### Full name of responsible person

Saman Ahmad Nasrollahi

#### Position

assistant professor

#### Other areas of specialty/work

#### Street address

No. 415, Taleqni Ave., Tehran, Iran

#### City

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#### Phone

+98 21 8897 7921

#### Fax

#### Email

samannasrol@gmail.com

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Tehran University of Medical science

#### Full name of responsible person

Alireza firooz

#### Position

professor

#### Other areas of specialty/work

#### Street address

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firozali@tums.ac.ir

#### Web page address

## Person responsible for updating data

### Contact

#### Name of organization / entity

Islamic azad university of pharmaceutical science

#### Full name of responsible person

Maedeh Sabet

#### Position

student

#### Other areas of specialty/work

#### Street address

Yakhchal street - Islamic Azad University Of Pharmaceutical Sciences Branch

#### City

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1941933111

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**Email**

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**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*