

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### Effect of Licorice extracts in the treatment of Melasma: randomized, double-blinded and placebo-controlled clinical trial

#### Protocol summary

##### Summary

Background: Melasma is a common acquired disorder characterized by symmetric, hyperpigmented patches with an irregular outline, occurring most commonly on the face. The goal of this study was to evaluate the skin-lightening ability and tolerability profile of a novel formulation, cream solid lipid nanoparticles containing licorice extracts in the treatment of melasma. This study was, to our knowledge, the first to show the efficacy of this novel formulation in the treatment of melasma all over the world. Methods: In this randomized, double-blinded and placebo-controlled clinical trial, 44 women patients with melasma clinically diagnosed referred to the Afzalipour hospital clinic were randomly divided into two treatment groups of 22 subjects each. All the patients were visited every four weeks from the beginning of the trial and evaluated MMASI score at 4, 8 and 12 weeks. The effectiveness of the treatment was classified in four levels as complete response, significant response, partial response and no response.

#### General information

##### Acronym

ELEOM

##### IRCT registration information

IRCT registration number: **IRCT2016040316016N2**

Registration date: **2016-04-11, 1395/01/23**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-04-11, 1395/01/23

##### Registrant information

###### Name

Siavash Mohammadzadeh Shanehsaz

##### Name of organization / entity

Kerman University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 34 1322 2251

##### Email address

siavash@kmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Kerman University of Medical Sciences, Deputy of research and technology

##### Expected recruitment start date

2014-09-23, 1393/07/01

##### Expected recruitment end date

2015-09-23, 1394/07/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of Licorice extracts in the treatment of Melasma: randomized, double-blinded and placebo-controlled clinical trial

##### Public title

Effect of Licorice extracts in the treatment of Melasma

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: 1- Patients with melasma clinically diagnosed 2- Women patients 3- Age between 20 to 40 years old 4- Patients with one lesion at least 5- Those don't use any treatment for melasma during the six months prior to commencement of the study. Exclusion criteria: 1- Pregnant women 2- Lactating women 3- Those

under treatment with other drugs for melasma during the six months prior to commencement of the study 4- Patients with history of allergy to licorice extracts 5- Treatment with oral contraceptives during of the study 6- Those under treatment with any drug for other diseases.

#### Age

From **20 years** old to **40 years** old

#### Gender

Female

#### Phase

3

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **44**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Kerman University of Medical Sciences, Deputy of research and technology

##### Street address

Kerman

##### City

Kerman

##### Postal code

#### Approval date

2015-03-10, 1393/12/19

#### Ethics committee reference number

93/293/15

## Health conditions studied

### 1

#### Description of health condition studied

Melasma or Chloasma

#### ICD-10 code

L81.1

#### ICD-10 code description

Other disorders of pigmentation

## Primary outcomes

### 1

#### Description

Size of lesions

#### Timepoint

Before and after intervention

#### Method of measurement

Examination

### 2

#### Description

Number of lesions

#### Timepoint

Before and after intervention

#### Method of measurement

Examination

### 3

#### Description

Location of lesions

#### Timepoint

Before intervention

#### Method of measurement

Examination

### 4

#### Description

Quality of life

#### Timepoint

Before and after intervention

#### Method of measurement

Questionare MELASQOL and DLQI

### 5

#### Description

Response to treatment

#### Timepoint

Before intervention and then at 4, 8 and 12 weeks

#### Method of measurement

Examination

### 6

#### Description

course of the disease

#### Timepoint

Before intervention

#### Method of measurement

Questionare

### 7

#### Description

Wood,s lamp examination

#### Timepoint

Before intervention

#### Method of measurement

Examination

## Secondary outcomes

1

### Description

Side effects

### Timepoint

After intervention

### Method of measurement

Examination

## Intervention groups

1

### Description

In intervention group: Treatment with cream of solid lipid nano particles containing licorice extracts 4%, BID (day and night) on the lesion along with cream sunscreen SPF=35

### Category

Treatment - Drugs

2

### Description

In control group: Treatment with cream placebo, BID (day and night) on lesion along with cream sunscreen SPF=35.

### Category

Placebo

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Afzalipour hospital, Kerman University of Medical Sciences

#### Full name of responsible person

Siavash Mohammadzadeh Shanehsaz

#### Street address

Kerman

#### City

Kerman

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Kerman University of Medical Sciences, Deputy of research and technology

#### Full name of responsible person

Siavash Mohammadzadeh Shanehsaz

#### Street address

Kerman

### City

Kerman

### Grant name

### Grant code / Reference number

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

Yes

### Title of funding source

Kerman University of Medical Sciences, Deputy of research and technology

### 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

Kerman University of Medical Sciences

#### Full name of responsible person

Siavash Mohammadzadeh Shanehsaz

#### Position

Dermatology resident

#### Other areas of specialty/work

#### Street address

Kerman

#### City

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#### Postal code

#### Phone

+98 34 3325 7560

#### Fax

#### Email

mdsiavash@yahoo.com

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Kerman University of Medical Sciences

#### Full name of responsible person

Siavash Mohammadzadeh Shanehsaz

#### Position

Dermatology resident

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Kerman University of Medical Sciences  
**Full name of responsible person**  
Siavash Mohammadzadeh Shanehsaz  
**Position**  
Dermatology resident  
**Other areas of specialty/work**  
**Street address**  
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**City**  
Kerman  
**Postal code**  
**Phone**  
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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*