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

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Name of organization / entity

Kerman University of Medical Sciences

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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/کا

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
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Web page address

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