

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Formulation and evaluation of the efficacy of topical preparation from Dorema ammoniacum D. Don oleo-gum-resin in patients with chloasma

Protocol summary

Study aim

Preparation of optimum semi-solid product from Dorema ammoniacum D. Don oleo-gum-resin; Determination of the physical and chemical parameters of the product and its quality control; Determine the efficacy of the product in patients with chloasma

Design

A, randomized, blinded, placebo controlled clinical trial with a parallel group design of 60 patients

Settings and conduct

recruitment of patients is carried out at Hajdahi clinic. The randomization of patients will be done using random numbers generated by computer and Excel. In this way, when every new patient enters the study, the researcher will be contacted by a third person. On the basis of a random number, the researcher will be informed that A or B is given to the patient. Patients and the person who provides the drug to patients will be unaware of the drug content.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Men and women aged 14_66 years old; The patients have mild to moderate melasma according to melasma severity index (MSI). Non inclusion criteria: The patients have used the bleaching materials during 2 weeks before intervention; Positive pregnancy test for female participants.

Intervention groups

Intervention group: topical preparation from Dorema ammoniacum D. Don oleo-gum-resin Control group: Eucerine Cream

Main outcome variables

severity of melasma

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141124020071N4**

Registration date: **2019-01-26, 1397/11/06**

Registration timing: **registered_while_recruiting**

Last update: **2019-01-26, 1397/11/06**

Update count: **0**

Registration date

2019-01-26, 1397/11/06

Registrant information

Name

Mohammad Hosein Farzaei

Name of organization / entity

Faculty of Pharmacy, Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-06, 1397/07/14

Expected recruitment end date

2019-10-06, 1398/07/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Formulation and evaluation of the efficacy of topical preparation from Dorema ammoniacum D. Don oleo-gum-resin in patients with chloasma

Public title

The efficacy of Dorema ammoniacum D. Don oleo-gum-resin on chloasma

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Being at the age of 14_66 years old Men and women The patients have mild to moderate melasma according to melasma severity index (MSI)

Exclusion criteria:

The patients have used the bleaching materials within 2 weeks before intervention Pregnancy test for female participants is positive

Age

From **14 years** old to **66 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Topical formulation of Dorema ammoniacum D. Don will give to the patients that chose based on the Block randomized method and divided into two groups including case and control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients and the person who provides the drug to patients will be unaware of the drug content.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Kermanshah University of Medical Sciences

Street address

Kermanshah University of Medical Sciences, Shahid Beheshti Blvd.

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Kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2018-12-19, 1397/09/28

Ethics committee reference number

IR.KUMS.REC.1397.743

Health conditions studied**1****Description of health condition studied**

chloasma

ICD-10 code

L81.1

ICD-10 code description

Chloasma

Primary outcomes**1****Description**

Chloasma

Timepoint

Before using the drug _ 30 days after the drug

Method of measurement

Based on Dermatology QOL (quality of life) Question and MSI (melasma severity index)

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: use of 1 grams topical preparation from Dorema ammoniacum D. Don oleo-gum-resin twice daily for 1 month.

Category

Treatment - Drugs

2**Description**

Control group: use of 1 grams Eucerine Cream twice daily for 1 month.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Haj Daie Medical clinic

Full name of responsible person

Fariba Najafi

Street address

Haj Daie Medical clinic, Golestan Ave., Kermanshah

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Behrooz Hamzeh

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Vice Chancellor for Research, Kermanshah University of Medical Sciences, Shahid Beheshti Blvd.,

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Kermanshah 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**

Kermanshah University of Medical Sciences

Full name of responsible person

Mohammad Hosein Farzaei

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

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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 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

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

Data Dictionary

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