Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Evaluating the effect of Myrobalan (Terminalia Chebula.) cream, 5% compared to hydroquinone cream, 2% in the treatment of melasma

Protocol summary

Study aim
Evaluating the Effectiveness of 5% Terminalia Chebula Retz. In Melasma Treatment

Design
This study is a randomized, double-blind clinical trial with a parallel group design of 48 patients

Settings and conduct
Patients are selected from Afzalipour Hospital of Kerman. Participants and physicians are blinded. The patients are assessed at baseline and after 4 and 8 and 12 weeks of using each cream based on Modified Melasma Area and Severity Index.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Women in the 18-55 age range with melasma Exclusion criteria: Pregnancy, lactation, antiepileptic drugs and spironolactone Thyroid disorders, polycystic ovary syndrome, anti-smear drug use during last 6 months, Use of oral and phototoxic contraceptives since last month, sensitivity to hydroquinone or Terminalia Chebula

Intervention groups
The treatment group use 5% cream containing the extract of Cable Harleys once in the night and the control group use 2% Hydroquinone

Main outcome variables
Modified Melasma Area and Severity Index (MMASI)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20110310006026N10**
Registration date: **2019-09-29, 1398/07/07**
Registration timing: **registered_while_recruiting**

Last update: **2019-09-29, 1398/07/07**
Update count: **0**

Registration date
2019-09-29, 1398/07/07

Registrant information
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-09-22, 1398/06/31

Expected recruitment end date
2020-01-19, 1398/10/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluating the effect of Myrobalan (Terminalia Chebula.) cream, 5% compared to hydroquinone cream, 2% in the treatment of melasma

Public title
"Effect of Terminalia Chebula in treatment of melasma"

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Women in the 18-55 age range with melasma
Exclusion criteria:

Pregnancy, lactation, antiepileptic drugs and spironolactone Thyroid disorders, polycystic ovary syndrome, anti-smear drug use during last 6 months, Use of oral and phototoxic contraceptives since last month, sensitivity to hydroquinone or Terminalia Chebula

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

1-2

Groups that have been masked

- Participant

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

The eligible participants are allocated to one of the two study groups in a 1:1 ratio. Allocation is by block randomization with a block size of four. A person (not involved in the trial) generates allocation sequence

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants and physician: The packaging of hydroquinone and Terminalia Chebula are similar in color and shape.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kerman University of Medical Sciences

Street address

Beginning of Jahad Blvd., Tahmasebad Fourways

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Province

Kerman

Postal code

7619813159

Approval date

2019-08-24, 1398/06/02

Ethics committee reference number

IR.KMU.REC.1398.254

Health conditions studied

1

Description of health condition studied

Melasma

ICD-10 code

L81.1

ICD-10 code description

Chloasma

Primary outcomes

1

Description

Melanin

Timepoint

At the beginning of treatment and at the end of weeks 4, 8 and 12

Method of measurement

Modified Melasma Area and Severity Index (MMASI)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 5% myrobalan cream which rub a thin layer of medicine every night and wash face in the morning.

Category

Treatment - Drugs

2

Description

Control group: 2% hydroquinone cream which rub a thin layer of medicine every night and wash face in the morning.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Afzali Pour hospital of Kerman

Full name of responsible person

Fatemeh Dabaghzadeh

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Sponsors / Funding sources

1

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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
Kerman 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
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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 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
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