

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Compare the effect of Kligman plus Methimazole 5% combination against Kligman alone in the treatment of melasma

Protocol summary

Study aim

Compare the effect of Kligman plus Methimazole 5% combination against Kligman alone in the treatment of melasma

Design

This study is a randomized, blinded clinical trial with a parallel group on 44 patients.

Settings and conduct

Each patient is given two creams with the same package shape, coded A and B, The evaluating physician and the patient are both unaware of the contents of the two creams. According to the table of random numbers each patient is randomly instructed to apply A cream to the left and B cream to the right of the face or vice versa. The severity of melasma lesions is measured according to the The Melasma area and severity index (MASI) at the beginning of the study and 8 weeks after the start of the drug intervention. Patient satisfaction is measured on a VAS scale after 8 weeks of treatment. This study was performed on patients with melasma referred to Alzahra Hospital in Isfahan.

Participants/Inclusion and exclusion criteria

Entry conditions: All patients with melasma No entry conditions: pregnancy, lactation, Treatment with OCP and HRT, Use of drugs that darken the color of the skin, History of allergy to topical and systemic steroids and thyroid drugs in at least the last 30 days, History of Severe systemic disease, History of any thyroid disease

Intervention groups

Each patient is given two creams, One of the creams contains Kligman(B) and another one contains Kligman and Methimazole(A). Each of the creams is rubbed on one side of the face(split face).

Main outcome variables

MASI score, Patient satisfaction, side effects

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200817048437N1**

Registration date: **2020-09-08, 1399/06/18**

Registration timing: **prospective**

Last update: **2020-09-08, 1399/06/18**

Update count: **0**

Registration date

2020-09-08, 1399/06/18

Registrant information

Name

Mahsa Akhtari Boroujeni

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3653 2286

Email address

mahsaakhtari@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-22, 1399/07/01

Expected recruitment end date

2022-03-20, 1400/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Compare the effect of Kligman plus Methimazole 5% combination against Kligman alone in the treatment of melasma

Public title

Effect of Kligman plus Methimazol in treatment of melasma

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

All patients with melasma

Exclusion criteria:

pregnancy lactation Treatment with OCP and HRT Use of drugs that darken the color of the skin History of allergy to topical and systemic steroids and thyroid drugs in at least the last 30 days History of Severe systemic disease History of any thyroid disease

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **44**

More than 1 sample in each individual

Number of samples in each individual: **2**

Right and left side of the face

Randomization (investigator's opinion)

Randomized

Randomization description

According to the table of random numbers each patient is randomly instructed to apply A cream to the left and B cream to the right of the face or vice versa.

Blinding (investigator's opinion)

Double blinded

Blinding description

Each patient is given two creams with the same package shape, coded A and B. The evaluating physician and the patient are both unaware of the contents of the two creams.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezarjarib Ave

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2020-06-06, 1399/03/17

Ethics committee reference number

IR.MUI.MED.REC.1399.206

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

Melasma

ICD-10 code

L81.1

ICD-10 code description

Chloasma

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

The severity of melasma lesions is measured according to the The Melasma area and severity index (MASI) , which includes three factors: percentage of facial involvement, darkness and homogeneity.

Timepoint

Measurement of the Melasma area and severity index (MASI score) at the beginning of the study and 8 weeks after the start of the drug intervention

Method of measurement

The Melasma area and severity index (MASI)

Secondary outcomes

empty

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

Intervention group: Each patient is given two creams, One of the creams contains Kligman(B) and another one contains Kligman and Methimazol(A). Each of the creams is rubbed on one side of the face (split face).

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center**

Name of recruitment center

Alzahra hospital
Full name of responsible person
Majid Rezvani
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alzahra@mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Shaghayegh Haghjooy javanmard
Street address
Isfahan university of medical sciences,Hezarjerib Ave
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8174673461
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research@mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person

Mahsa Akhtari Boruojeni
Position
Resident
Latest degree
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Other areas of specialty/work
Dermatology
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Person responsible for updating data

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Dermatology

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

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Data are published that have nothing to do with the
personality and identity of the participants in this study
and are only the results of the study.

When the data will become available and for how long

The data are available six months after the publication of
the article in the journal.

To whom data/document is available

Approved university researchers are allowed to access
the data after being authenticated by the relevant
university.

Under which criteria data/document could be used

The data can only be used for research purposes, such
as writing review articles.

From where data/document is obtainable

To receive the data, the corresponding author can be
accessed via the email and telephone number of the
university mentioned in the article.

What processes are involved for a request to access data/document

After reviewing the data access request, if approved, it is
for non-industrial and non-commercial uses, the data will
be provided to the applicant.

Comments