

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the efficacy of Klingman Combination cream in comparison with Cysteamine 5% cream on the severity of epidermal Melasma.

Protocol summary

Study aim

Determination of the effectiveness of Klingman Combination cream in Comparison with Cysteamine 5% Cream on the severity of epidermal Melasma.

Design

The clinical trial with two groups (intervention and control), pragmatic, double-blind, randomized

Settings and conduct

This study will be conducted to evaluate the effect of Cysteamine 5% cream in comparison with Klingman Combined Formula on the severity of epidermal melasma in a specialized clinic of Vasesi Hospital in Sabzevar. Patients will be randomly assigned to intervention group 1 (Cysteamine 5% cream) and Intervention 2 (Klingman Combined cream). The response to treatment will be evaluated MASI (Melasma Area Severity Index) index and Derma catch® score for the groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 20 and 50 years, Patients whose illness have been lasted more than 6 months, Patients who have not received any medication for at least 2 months. Exclusion Criteria: History of Endocrine diseases, pregnancy and breastfeeding, Any Corticosteroids treatment 3 months before study, Use of oral contraceptive pills before study, Other skin diseases.

Intervention groups

First intervention group: Patients treated with Cysteamine 5% cream for 6 months at night for 15 minutes, then washing with lukewarm water and then using a moisturizing cream (Emolene cream). Sunscreen will also be used throughout the day. Second intervention group: Patients treated with Klingman Combined cream for 6 months at night, then washing with lukewarm water and then using a moisturizing cream (Emolene cream). Sunscreen will also be used throughout the day.

Main outcome variables

Determine the severity of the area involved in Melasma

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181006041252N3**

Registration date: **2018-12-17, 1397/09/26**

Registration timing: **registered_while_recruiting**

Last update: **2018-12-17, 1397/09/26**

Update count: **0**

Registration date

2018-12-17, 1397/09/26

Registrant information

Name

Mohammad Sahebkar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 4401 8337

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sahebkar@medsab.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-29, 1397/08/07

Expected recruitment end date

2018-12-28, 1397/10/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the efficacy of Klingman Combination cream in comparison with Cysteamine 5% cream on the severity of epidermal Melasma.

Public title

Evaluation of the efficacy of Klingman Combination cream in comparison with Cysteamine 5% cream on the severity of epidermal Melasma.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 20 and 50 years Patients who have not received any medication for at least 2 months Patients whose illness have been lasted more than 6 months

Exclusion criteria:

History of Endocrine diseases, pregnancy, and breastfeeding; Any Corticosteroids treatment 3 months before study; Use of oral contraceptive pills before study; Other skin diseases.

Age

From **20 years** old to **50 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be conducted based on a permutation block, Accordingly, 25 blocks will be designed and each block will be composed by 2 of each following groups, treatment group A and group B. Eventually, after completing the blocks, Group A and B will be treated with Cysteamine 5% cream and Klingman combination cream, respectively.

Blinding (investigator's opinion)

Double blinded

Blinding description

A study code A or B will be assigned to each person which only the researcher will know the type of groups. The person who will evaluate the outcome and the participants will be unaware of the groups. It should be noted that Cysteamine and Klingman combination cream will be similar in appearance, color, and packaging.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Sabzevar University of Medical Sciences

Street address

Sabzevar University of Medical Sciences, Tohid Blvd, Sabzevar city

City

Sabzevar

Province

Razavi Khorasan

Postal code

9617913114

Approval date

2018-10-29, 1397/08/07

Ethics committee reference number

IR.MEDSAB.REC.1397.048

Health conditions studied

1

Description of health condition studied

Epidermal Melasma

ICD-10 code

L85

ICD-10 code description

Other epidermal thickening

Primary outcomes

1

Description

Determine the severity of the area involved in Melasma

Timepoint

In the 2nd and 4th months after the starting intervention for the Cysteamine and Klingman group

Method of measurement

Based on Derma catch® score and MASI index (Melasma Area Severity Index)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients will be treated with Cysteamine 5% cream for 6 months at night for 15 minutes, then will wash with lukewarm water and then will use moisturizing cream (Emolene cream). Sunscreen will also be used throughout the day.

Category

Treatment - Drugs

2

Description

Intervention group: Patients will be treated with Klingman cream for 6 months at night, then will wash with lukewarm water and then will use moisturizing cream (Emolene cream). Sunscreen will also be used throughout the day.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Vasei hospital

Full name of responsible person

Mohammad Sahebkar

Street address

Vasei Hospital, Asadabady Ave., Sabzevar Town

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Dr. Fereshte Ghorat

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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

Sabzevar 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

Sabzevar University of Medical Sciences

Full name of responsible person

Dr. Maryam Karrabi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

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Position

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Latest degree

Specialist

Other areas of specialty/work

Dermatology

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Person responsible for updating data**Contact****Name of organization / entity**

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Position

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Latest degree

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Other areas of specialty/work

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

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

Study Protocol

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

Statistical Analysis Plan

Not applicable

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

No - There is not a plan to make this available

Data Dictionary

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