

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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)

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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	
<u>1</u>	
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	
<u>1</u>	
Description of health condition studied	Epidermal Melasma
ICD-10 code	L85
ICD-10 code description	Other epidermal thickening
Primary outcomes	
<u>1</u>	
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	
<u>1</u>	
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

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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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Person responsible for scientific inquiries

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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