Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 Cystamine 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
Email address
sahebkarm@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 e 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
City
Sabzevar
Province
Razavi Khorasan
Postal code
9613873136
Phone
+98 51 4401 8337
Email
Mohammad.sahebkar66@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Sabzevar University of Medical Sciences
Full name of responsible person
Dr. Fereshte Ghorat
Street address
Sabzevar University of Medical Sciences, Tohid Blvd., Sabzevar Town
City
Sabzevar
Province
Razavi Khorasan
Postal code
9617913114
Phone
+98 51 4401 8319
Email
Drghorat@gmail.com
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
Street address
Sabzevar University of Medical Sciences, Tohid Blvd., Sabzevar Town
City
Sabzevar
Province
Razavi Khorasan
Postal code
9617913114
Phone
+98 51 4401 8337
Email
Marikori90@gmail.com

Person responsible for scientific 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
Street address
Sabzevar University of Medical Sciences, Tohid Blvd., Sabzevar Town
City
Sabzevar
Province
Razavi Khorasan
Postal code
9617913114

Phone
+98 51 4401 8337
Email
Marikori90@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Sabzevar University of Medical Sciences
Full name of responsible person
Mohammad Sahebkar
Position
Consultant
Latest degree
Master
Other areas of specialty/work
Epidemiology
Street address
Sabzevar University of Medical Sciences, Tohid Blvd., Sabzevar Town
City
Sabzevar
Province
Razavi Khorasan
Postal code
9617913114
Phone
+98 51 4401 8337
Email
Mohammad.sahebkar66@gmail.com

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