Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of the effect of Cysteamine 5% cream with Tranexamic acid Mesotherapy on the severity of epidermal Melasma.

Protocol summary

Study aim
Determination of the effectiveness of Cysteamine 5% cream compared with Tranexamic acid mesotherapy on the severity of epidermal Melasma.

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

Settings and conduct
This study will be conducted to evaluate the effect of Cysteamine 5% cream in comparison with Tranexamic acid mesotherapy 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 (Tranexamic acid Mesotherapy). The response to treatment is evaluated MASI (Melasma Area Severity Index) index and Derma catch® score for the intervention groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age between 20 and 50 years, Patients who have been at least 6 months old since their illness, 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 in this group use Cysteamine 5% cream at night for 2 months. Second Intervention group: In this group, 4 mg/cc of Tranexamic acid will be injected intradermally every 4 weeks, and the skin of the patient was rinsed with normal saline and then anesthetized with local anesthetic ointment (ELMA) for 40 to 60 minutes, and then, the Tranexamic acid is injected at intervals of 10 mm from the involved area to three areas for full coverage of the lesion using an insulin syringe (Nidel 28J) under sterile conditions. In addition, the injectable dose will not exceed 8 mg/cc during three injections per injection.

Main outcome variables
Determine the severity of the area involved in Melasma

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20181006041252N2**
Registration date: **2018-11-29, 1397/09/08**
Registration timing: **registered_while_recruiting**

Last update: **2018-11-29, 1397/09/08**
Update count: **0**

Registration date
2018-11-29, 1397/09/08

Registrant information
Name
Mohammad Sahebkar
Name of organization / entity
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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
Comparison of the effect of Cysteamine 5% cream with Tranexamic acid Mesotherapy on the severity of epidermal Melasma.

Public title
Comparison of the effect of Cysteamine 5% cream with Tranexamic acid Mesotherapy on the severity of epidermal Melasma.

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age between 20 and 50 years Patients who have been at least 6 months old since their illness Patients who have not received any medication for at least 2 months

Exclusion criteria:
History of Endocrine diseases, pregnancy and breast feeding 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

- Outcome assessor

Sample size
Target sample size: **54**

Randomization (investigator's opinion)
Randomized

Randomization description
Block randomization based on permutation. Accordingly, 27 blocks were allocated to patients, in each block 2 from A treatment group and 2 from the B treatment group were placed. Eventually, after completion of the blocks, group A was treated with Cysteamine 5% cream and Group B treated with Tranexamic Acid Mesotherapy.

Blinding (investigator's opinion)
Single blinded

Blinding description
Each person in the study will be assigned code A and B, that the researcher will only be known of the type of groups. The outcome evaluator is unaware of the groups.

Placebo
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.1397.053

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
Week 4 and 8 after starting the intervention for Tranexamic acid and months 2 and 4 after the intervention for the Cysteamine 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 in this group use cysteamine 5% cream at night for 2 months, and also during a day they use a sunscreen with SPF 25% with zinc oxide 7.5% daily.

Category
Treatment - Drugs

2

Description
Intervention group: In this group, 4 mg/cc of tranexamic acid will be injected intradermally every 4 weeks, and The skin of the patient was rinsed with normal saline and then anesthetized with local anesthetic ointment (ELMA) for 40 to 60 minutes, and then, the tranexamic acid is injected at intervals of 10 mm from the involved area to three areas for full coverage of the lesion using an insulin syringe (Nidel 28J) under sterile conditions. In addition, the injectable dose will not exceed 8 mg/cc during three injections per injection. During a day they will use a sunscreen with SPF 25% with zinc oxide 7.5% daily

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Vasei hospital

Full name of responsible person
Yegane AbdollahNejad Nasiri

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
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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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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