

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 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

Country

Iran (Islamic Republic of)

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+98 51 4401 8337

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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

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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