Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of the effectiveness of mesotherapy with glutathione versus mesotherapy with tranexamic acid in the treatment of patients with melasma

Protocol summary

Study aim
Comparison of the effectiveness of mesotherapy with glutathione versus mesotherapy with tranexamic acid in the treatment of patients with melasma

Design
A randomized, double-blind, parallel-group, phase III clinical trial was conducted in 42 patients. Randomization was performed using a random number table.

Settings and conduct
The study will be conducted at the Dermatology Clinic of Imam Khomeini Hospital, Ahvaz. After obtaining informed consent, eligible patients will be randomly assigned to undergo glutathione and tranexamic acid mesotherapy on both sides of the face with the same injection protocol. Evaluation of response to treatment and complications will be performed in a double-blind manner, and only the independent researcher will be aware of the coding of the syringes.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Women aged 18 to 60 years with bilateral facial melasma, no use of topical or systemic melasma in the last 3 months. Exclusion criteria: Pregnancy and lactation, use of oral contraceptives, history of thrombotic diseases and coagulation disorders, Hypersensitivity to the study drugs or lidocaine, presence of active infectious lesions on the face.

Intervention groups
Intervention Group 1 (Glutathione): Mesotherapy with glutathione 0.6% (Sina Darou), diluted with 2% lidocaine (10:1 ratio), intradermal injection using insulin syringe (30G needle), depth 1mm, volume 0.05ml, point spacing 1cm, 5 sessions every 2 weeks. Intervention Group 2 (Tranexamic Acid): Mesotherapy with tranexamic acid 4mg/ml (Aburayhan), diluted with 2% lidocaine (10:1 ratio), intradermal injection using insulin syringe (30G needle), depth 1mm, volume 0.05ml, point spacing 1cm, 5 sessions every 2 weeks. Care: Topical anesthetic cream (Xylapin) before injection and sunscreen SPF 50 after injection.

Main outcome variables
Melasma Area and Severity Index score

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260801070468N1**
Registration date: **2026-09-20, 1405/06/29**
Registration timing: **prospective**

Last update: **2026-09-20, 1405/06/29**
Update count: **0**

Registration date
2026-09-20, 1405/06/29

Registrant information

Name
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Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-10-03, 1405/07/11

Expected recruitment end date
2028-10-02, 1407/07/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of mesotherapy with glutathione versus mesotherapy with tranexamic acid in the treatment of patients with melasma

Public title

Comparison of glutathione mesotherapy and tranexamic acid mesotherapy for treatment of melasma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Female patients aged 18–60 years with bilateral symmetrical facial melasma Not receiving treatment for melasma within three months prior to study entry Willingness to participate in the study Signing a written informed consent form

Exclusion criteria:

Pregnant or breastfeeding women Use of oral contraceptive pills during the previous 12 months or planned use during the study period History of coagulation disorders or thrombotic diseases Current use of anticoagulant or anticonvulsant medications Known hypersensitivity to the study medications or topical lidocaine Presence of active infectious skin diseases, such as warts or active herpes, at the treatment site History of systemic diseases associated with hyperpigmentation

Age

From **18 years** old to **60 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **42**

Randomization (investigator's opinion)

Randomized

Randomization description

Given the split-face study design, randomization was performed to determine which side of the face (left or right) would receive each of the two interventions; consequently, each participant received both interventions on opposite sides of the face. The allocation sequence was generated prior to participant enrollment using the "Sealed Envelope" online system, which randomly determined the order of the two possible allocation scenarios (Intervention A on the left and Intervention B on the right, or Intervention B on the left and Intervention A on the right). A randomization code was then assigned to each participant, dictating the random allocation of the left and right sides of the face to Interventions A and B. Allocation codes remained concealed from the researchers responsible for participant enrollment and outcome assessment until the time of allocation, ensuring that the assignment could not be predicted beforehand.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is double-blinded. The participants (patients), the clinical caregiver (injecting physician), and the outcome assessor (MASI scoring physician) are blinded to the treatment group assignment. Blinding is implemented by an independent research associate who is not involved in the patient assessment process, using a random number table, determining which side of the face will be treated with each drug and preparing the drugs in identical, coded syringes (coded A and B). The coded syringes are then provided to the injecting physician to perform the injection process. The injecting physician is unaware of the type of drug injected. The patient (participant) is also unaware of the type of drug injected into each side of the face and does not know which side was treated with which drug. The evaluator (scorer) who scores the MASI and PGA before and after treatment is completely unaware of the treatment allocation and coding of the syringes and only reviews the photographs taken and the patient's clinical condition. Therefore, in this study, the three groups including the participants (patients), the clinical caregiver (injecting physician), and the outcome assessor (scoring physician) are blinded to the treatment group allocation, and only an independent research associate who has no role in the patient assessment process is aware of the coding of the syringes and random allocation. Blinding is done with the full knowledge of the participants and obtaining written informed consent.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Jundishapur University of Medical Sciences، Golestan St، Ahvaz

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Province

Khouzestan

Postal code

6193673166

Approval date

2026-07-25, 1405/05/03

Ethics committee reference number

IR.AJUMS.REC.1405.181

Health conditions studied

1

Description of health condition studied

Melasma

ICD-10 code

L81.1

ICD-10 code description

Chloasma

Primary outcomes

1

Description

Melasma Area and Severity Index score

Timepoint

Before treatment initiation and at weeks 4, 8, and 12 after treatment initiation

Method of measurement

Assessment of the Melasma Area and Severity Index using the standardized Melasma Area and Severity Index scoring system by a dermatologist

2

Description

Patient Global Assessment score

Timepoint

Before treatment initiation and at weeks 4, 8, and 12 after treatment initiation

Method of measurement

Assessment of the Patient Global Assessment using a standardized scoring scale by a dermatologist

3

Description

Physician Global Assessment (PGA) score

Timepoint

Weeks 4, 8, and 12 after the start of the study

Method of measurement

Comparison of before and after treatment photos by the evaluating physician based on the grading of Excellent (75% improvement), Good (51-75%), Fair (26-50%), and Poor (0-25%)

4

Description

Incidence of adverse events related to mesotherapy

Timepoint

Immediately after each treatment session and until the end of the study period

Method of measurement

Review and record of complications including erythema, edema, ecchymosis, pain, and local sensitivity by the treating physician.

5

Description

Patient satisfaction score

Timepoint

End of treatment period (week 12)

Method of measurement

Questioning the patient based on a 5-point scale (1: Dissatisfied, 2: Slightly satisfied, 3: Relatively satisfied, 4: Good satisfaction, 5: Completely satisfied)

6

Description

Melasma recurrence rate at 3 months after treatment

Timepoint

3 months after the last treatment session (week 24)

Method of measurement

Recalculation of MASI Score and comparison with previous scores by the evaluating physician

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: One half of each participant's face, randomly selected, will undergo glutathione mesotherapy from the manufacturer Sina Darou. The injection will be performed intradermally with a 30-gauge needle (insulin syringe), at a depth of approximately 1 mm, with a volume of 0.05 ml at each point, and with a distance of approximately 1 cm between injection points. The injection solution will be diluted with 10% 2% lidocaine according to the study protocol, and the intervention will be performed in 5 sessions with an interval of two weeks. The patient will be evaluated before each session and will be examined for side effects including erythema, edema, and ecchymosis after each session.

Category

Treatment - Drugs

2

Description

Intervention group 2: Tranexamic acid with the chemical formula $C_8H_{15}NO_2$ at a concentration of 4 mg/ml (manufactured by Aburayhan Pharmaceutical Company, Iran) is diluted with 2% lidocaine at a ratio of 10:1. The dosage administered in each session is 2 ml of the final solution (containing 8 mg of pure tranexamic acid), which is injected as intradermal microinjection using a 1

ml insulin syringe with a 30-gauge needle at points spaced 1 cm apart, with a volume of 0.05 ml per point and a depth of 1 mm. Treatment sessions are conducted in 5 sessions at 2-week intervals (weeks 0, 2, 4, 6, and 8). Pre-injection care includes application of topical anesthetic cream (Xylapin) for 20 minutes, and post-injection care includes daily use of sunscreen with SPF 50 and avoidance of direct sunlight for 48 hours.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Khomeini Hospital., Dermatology Clinic
Full name of responsible person
Tara Barat
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Sponsors / Funding sources

1

Sponsor

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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
Ahvaz 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
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Tara Barat
Position
Assistant Professor of Dermatology
Latest degree
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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
Undecided - It is not yet known if there will be a plan to make this available

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

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