Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of the Efficacy and Safety of Oral Versus Intradermal Tranexamic Acid in the Treatment of Melasma: A Randomized Clinical Trial

Protocol summary

Study aim

To compare the efficacy and safety of oral tranexamic acid with intradermal tranexamic acid mesotherapy in women with melasma.

Design

A parallel-group randomized clinical trial with 1:1 allocation using a random number table.

Settings and conduct

Eligible participants will be evaluated at baseline and followed during treatment and the post-treatment follow-up period. Clinical assessment will be performed using the modified Melasma Area and Severity Index (mMASI), MELASQoL, and standardized facial imaging with VisioFace and DermLite 4

Participants/Inclusion and exclusion criteria

Women aged 18–45 years with clinically diagnosed melasma and Fitzpatrick skin phototypes I–IV will be enrolled. Exclusion criteria include a history of venous or arterial thrombosis, thromboembolic disorders or predisposition to thrombosis, significant coagulation disorders, concomitant medications affecting coagulation that may make participation inappropriate, pregnancy or breastfeeding, known hypersensitivity to tranexamic acid, severe renal disease or significant renal impairment, history of seizures, severe systemic conditions that may interfere with study participation or safety assessment, active skin disease at the injection site, and recent treatments for melasma that may interfere with treatment response.

Intervention groups

Participants two treatment groups. oral tranexamic acid group will receive tranexamic acid 250 mg twice daily for 12 weeks. The intradermal tranexamic acid mesotherapy group will receive intradermal tranexamic acid injections every 2 weeks for 12 weeks.participants will receive sunscreen SPF 50 and standardized sun-avoidance advice.

Main outcome variables

change in mMASI score from baseline to 12 weeks after treatment initiation. visual analogue scale (VAS), recurrence of melasma during the 3-month post-treatment follow-up period, and treatment-related adverse events.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220117053743N4**
Registration date: **2026-11-16, 1405/08/25**
Registration timing: **prospective**

Last update: **2026-11-16, 1405/08/25**
Update count: **0**

Registration date

2026-11-16, 1405/08/25

Registrant information

Name

Aida Farmani

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 31 3261 6408

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-11-20, 1405/08/29

Expected recruitment end date

2027-05-19, 1406/02/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Efficacy and Safety of Oral Versus Intradermal Tranexamic Acid in the Treatment of Melasma: A Randomized Clinical Trial

Public title

Comparison of the Efficacy and Safety of Oral Versus Intradermal Tranexamic Acid in the Treatment of Melasma: A Randomized Clinical Trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Women aged 18–45 years.Clinical diagnosis of facial melasma.Presence of melasma on the face.Willingness to participate and signing written informed consent.No recent 3 months use of systemic or topical treatments that may significantly affect melasma.

Exclusion criteria:

A history of venous or arterial thrombosis.Thromboembolic disorders or a known predisposition to thrombosis.Significant coagulation disorders.Concomitant use of medications affecting coagulation that may make participation in the study inappropriate.Pregnancy or breastfeeding.Known hypersensitivity to tranexamic acid.Severe renal disease or significant renal impairment.A history of seizures.Severe systemic diseases or medical conditions that, in the investigator’s judgment, may interfere with study participation or affect the safety or assessment of the treatment.Active skin disease at the injection site.Recent use of treatments for melasma that may interfere with the assessment of treatment response.

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be randomly allocated to the two study groups in a 1:1 ratio using a random number table.

Blinding (investigator's opinion)

Single blinded

Blinding description

The study will use single-blind methodology, in which the data analyst will be blinded to the treatment allocation throughout the statistical analysis.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

دانشکده پزشکی - دانشگاه علوم پزشکی اصفهان (کمیته اخلاق در پژوهش)

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Isfahan . medical University

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Isfehan

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8158799346

Approval date

2026-07-22, 1405/04/31

Ethics committee reference number

IR.MUI.MED.REC.1405.171

Health conditions studied

1

Description of health condition studied

Chloasma

ICD-10 code

L81.1

ICD-10 code description

Chloasma

Primary outcomes

1

Description

Change in the modified Melasma Area and Severity Index (mMASI) score, reflecting the severity of melasma based on the extent and intensity of pigmentation in the affected facial areas.

Timepoint

At baseline (before initiation of treatment) and at 12 weeks after treatment initiation.

Method of measurement

The mMASI score will be assessed clinically by a dermatologist using standardized evaluation of the extent and intensity of facial hyperpigmentation in the four facial regions (forehead, right malar, left malar, and chin). The score will be calculated according to the

standard mMASI scoring system.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: oral Tranexamic acid 250 mg BID
Category
Treatment - Drugs

2

Description
Control group: Intradermal Tranexamic acid 100mg/cc
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
کلینیک های درماتولوژی وابسته به دانشگاه علوم پزشکی اصفهان به انگلیسی
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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
Esfahan 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
Esfahan University of Medical Sciences
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Assistant Professor
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Due to ethical considerations, participant privacy, and the need to ensure appropriate data protection, individual participant data will not be made publicly available. De-identified data may be considered for sharing upon reasonable request, subject to approval by the principal investigator and compliance with institutional and ethical requirements.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available