

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

Comparison of the Effectiveness of intradermal injected tranexamic acid 50mg/ml plus ascorbic acid 50mg/ml VS tranexamic acid 50mg/ml in the treatment of melasma: A split face comparative trial

Protocol summary

Study aim

Comparison of the efficacy of intradermal injected Tranexamic acid 50mg/ml with 50mg / ml Ascorbic acid on one side of the face with intradermal injected Tranexamic acid 50mg/ml and the other side of the face

Design

Comparative split face randomised clinical trial, with control group, parallel group, with 24 person in each group. RCT is in phase 3.

Settings and conduct

The study will be performed on patients who referred with facial melasma in Dermatology Clinic of Ahwaz Imam Khomeini Hospital. Patients are blinded about the type of medication injected.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 18-50 years old women; with bilateral facial melasma. Exclusion criteria: Pregnant and lactating women; Oral contraceptive pill consumption in 12 months ago during RCT; History of coagulopathy and thrombotic disorder; Anticoagulant and antiepileptic drug consumption; Sensitivity to tranexamic acid; History of treatment for melasma during 1 month ago; Active facial herpes simplex virus infection; Facial wart

Intervention groups

One side of the face is injected with tranexamic acid 50 mg / ml and ascorbic acid 50 mg / ml intradermally every other week for 12 weeks. The opposite side of the face is injected with tranexamic acid 50 mg / ml intradermally every other week for 12 weeks.

Main outcome variables

Melasma area and severity index; Patients satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191213045719N1**

Registration date: **2020-01-26, 1398/11/06**

Registration timing: **registered_while_recruiting**

Last update: **2020-01-26, 1398/11/06**

Update count: **0**

Registration date

2020-01-26, 1398/11/06

Registrant information

Name

Seyedeh Nasrin Molavi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-23, 1398/09/02

Expected recruitment end date

2020-08-23, 1399/06/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effectiveness of intradermal injected tranexamic acid 50mg/ml plus ascorbic acid 50mg/ml VS tranexamic acid 50mg/ml in the treatment of melasma: A

split face comparative trial

Public title

"Effect of Ascorbic acid in treatment of melasma"

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Women at the range of 18 to 50 years old patients with symmetrical bilateral melasma

Exclusion criteria:

Patient who is pregnant or in lactation period
Patient who had taken oral contraceptive pill in 12 months ago
Patient who has history of coagulopathy and thrombotic disorder
Patient who is taking anticoagulant and antiepileptic drug
Patient who has sensitivity to tranexamic acid
Patient who has history of treatment for melasma during 1 month ago
Patient who has active facial herpes simplex virus infection
Patient who has facial wart

Age

From **18 years** old to **50 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **24**

More than 1 sample in each individual

Number of samples in each individual: **2**

Right side of one person's face and left side of the same person's face

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization will be done by coin toss. The coin will be thrown into the air several times (based on the number of study samples) and we will check which side is showing when it will land. If it will land from the head, the right side of the face will put in group A (tranexamic acid and ascorbic acid) and if it will land on the tail, the right side of the face will put in group B (tranexamic acid and placebo). Left side of the face. Then left side of the face will put in the other group.

Blinding (investigator's opinion)

Single blinded

Blinding description

Due to the uniformity of the color and similarity of the appearance of the injected medication, participants and value assessment will be blinded to the medication given at any side of their faces.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahwaz Jondishapur University of Medical Sciences

Street address

Vice Chancellor for Research, Ahwaz Jondishapur University of Medical Sciences; Golestan Blvd

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Khuzestan

Postal code

6193673166

Approval date

2019-11-23, 1398/09/02

Ethics committee reference number

IR.AJUMS.REC.1398.623

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

Timepoint

Melasma area and severity index measured at base of trial and 4, 8, 12 and 24 weeks of trial

Method of measurement

Melasma area and severity index

Secondary outcomes

1

Description

Patient satisfaction

Timepoint

Measuring of patient satisfaction in 4, 8, 12 and 24 weeks of trial

Method of measurement

Satisfaction percentage questionnaire

Intervention groups

1

Description

Intervention group: One side of the face is injected with Tranexamic acid 50 mg / ml and Ascorbic acid 50 mg / ml is given intradermally every other week for 12 weeks.

Category

Treatment - Drugs

2

Description

Control group: The other side of the face is injected with tranexamic acid 50 mg / ml intradermally every other week for 12 weeks. Tranexamic acid is available in 500 mg ampoules at 5 cc. Ascorbic acid is available in 500 mg ampoules at 5 cc.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Doctor Seyedeh Nasrin Molavi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz 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

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

Ahvaz University of Medical Sciences

Full name of responsible person

Doctor Seyedeh Nasrin Molavi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

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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