Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of the Effectiveness of intradermal injected tranexamic acid50mg/ml plus ascorbic acid50mg/ml VS tranexamic acid50mg/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 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 week12 weeks.The opposite side of the face is injected with tranexamic acid 50 mg / ml intradermaly 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

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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 acid50mg/ml plus ascorbic acid50mg/ml VS tranexamic acid50mg/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 ia 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,righte side of the face will put in groupe A(tranxamic acid and ascorbic acid) and if it will land on the tail, righte side of the face will put in groupe B(tranxamic acid and placebo).left side of the face.Then left side of the face will put in the other groupe.
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 Jundishapur University of Medical Sciences; Golestan Blvd
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Khouzestan
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 and24 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 intradermaly 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
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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
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
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Ahvaz University of Medical Sciences
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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