Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of the efficacy of intradermal injecting of tranexamix acid and hydroquinone cream in the treatment of melasma

Protocol summary

Study aim
Comparison of the effect of intranasal injection of tranexamic acid 100 mg / ml in comparison with topical hydroquinone cream 4% in the treatment of melasma

Design
In this clinical trial which is parallel group, double-blind, randomized, phase 3 trial, 48 people who will refer to the dermatology clinic of Imam Khomeini Hospital in Ahwaz will participate.

Settings and conduct
This study will be carried out in the dermatology clinic of Imam Khomeini Hospital in Ahvaz and among the clients who will refereed for the treatment of melasma.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Female, age of 18-50 years old, with facial melasma. Exclusion criteria: Pregnant and lactating women, history of melasma treatment during the past month, active facial Herpes simplex lesions, Any history of coagulopathy and thrombotic problems

Intervention groups
Intervention group 1: intradermal injection of tranexamic acid ampoule into melasma areas will be performed at 2 weeks intervals for 3 months. Intervention group 2: treatment with topical 4% hydroquinone will be performed. The duration of treatment will be 12 weeks, and the response will be evaluated every 4 weeks

Main outcome variables
The degree of melasma treatment

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180909040979N5**
Registration date: **2020-01-03, 1398/10/13**
Registration timing: **registered_while_recruiting**
Last update: **2020-01-03, 1398/10/13**
Update count: **0**

Registration date
2020-01-03, 1398/10/13

Registrant information

Name
MARYAM ZAMANKHANI

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-12-07, 1398/09/16

Expected recruitment end date
2020-09-06, 1399/06/16

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the efficacy of intradermal injecting of tranexamix acid and hydroquinone cream in the treatment of melasma

Public title
The effect of tranexamic acid and hydroquinone in melasma

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Female sex Being at the age of 18-50 years old Facial melasma
Exclusion criteria:
Pregnant and lactating women History of melasma treatment over the past month Active herpes simplex lesions on the face Sensitivity to the drugs in the study Coagulopathy Warts on the face Use of anticoagulant and anticonvulsant drugs Contraceptive use during the past 12 months and during the study

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

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **48**

Randomization (investigator's opinion)
Randomized

Randomization description
Individuals are randomly divided into two groups based on block randomization method. Randomized blocks are used for this purpose. A random sample based on this method from Sealedenvelope.com has been extracted.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Ahvaz University of Medical Sciences

Street address
Vice Chancellor for Research; Ahvaz Jundishapur University of Medical Sciences; Golestan blvd

City
Ahvaz

Province
Khouzestan

Postal code
6193673166

Approval date
2019-12-07, 1398/09/16

Ethics committee reference number
IR.AJUMS.REC.1398.652

Health conditions studied

1

Description of health condition studied
Melasma

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
The degree of melasma treatment

Timepoint
Before treatment, at 4th, 8th and 12th week during the treatment and three months after the end of the treatment

Method of measurement
MASI score

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: In group A, after application of topical anesthetic cream (lidocaine + prilocaine) 30 minutes before injection, tranexamic acid ampule, 100 mg/ml (manufactured by Caspian Supply Company) will be injected intradermally into melasma areas at 1 cm intervals, every 2 weeks for 3 months. The 1CC insulin syringe will be used for injection.

Category
Treatment - Drugs

2

Description
Intervention group 2: Group B will be treated with topical hydroquinone 4% every night. The duration of treatment will be 12 weeks, and the response will be evaluated every 4 weeks.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Khomeini Hospital

Full name of responsible person
Nader Pazyar

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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
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Position
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Latest degree
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Person responsible for updating data

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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
No decision has been made yet
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
Undecided - It is not yet known if there will be a plan to make this available