

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 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 tranexamix 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 Ahwaz and among the clients who will be referred 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 tranexamix 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 tranexamix 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

Khuzestan

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
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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
Motahareh Babazadeh
Position
Rezident
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