

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the Efficacy of Intradermal injected Tranexamic Acid vs Hydroquinone cream in the Treatment of Melasma

Protocol summary

Study aim

- Comparison of the efficacy of 4 and 10 mg/ml intradermal injected Tranexamic Acid vs 4% Hydroquinone cream in the treatment of melasma - Comparison of incidence of adverse effect of Tranexamic acid between two therapeutic

Design

Split face randomised blinded parallel control group trial with 20 person at each group. RCT is in phase II

Settings and conduct

Patients with inclusion criteria divided in two groups with permuted four block randomization at dermatology departemant of Imam Hospital in Ahwaz city. Right face treated with intradermal of tranexamic acid with 4 mg/ml in one group 10 mg/ml in another group every other week for 12 weeks and left face treated with hydroquinon 4% twice a day for 12 weeks. Patients and value assessment blind to dose of Tranexamic acid.

Participants/Inclusion and exclusion criteria

- Inclusion criteria: Women with symmetrical bilateral melasma who signature the letter of satisfaction - 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

Right face treated with intradermal of tranexamic acid with 4 mg/ml in one group 10 mg/ml in another group every other week for 12 weeks and left face treated with hydroquinon 4% twice a day for 12 weeks

Main outcome variables

Decrease in melasma area and severity index ; Increase patients satisfaction

General information

Reason for update

Acronym

AMS

IRCT registration information

IRCT registration number: **IRCT20180203038599N1**

Registration date: **2018-03-26, 1397/01/06**

Registration timing: **retrospective**

Last update: **2018-03-26, 1397/01/06**

Update count: **0**

Registration date

2018-03-26, 1397/01/06

Registrant information

Name

Maryam Zeynalie

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3392 4392

Email address

zeynalie.m@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-08-23, 1396/06/01

Expected recruitment end date

2018-01-21, 1396/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Efficacy of Intradermal injected Tranexamic Acid vs Hydroquinone cream in the Treatment of Melasma

Public title

Comparison of the Efficacy of Intradermal injected Tranexamic Acid vs Hydroquinone cream in the Treatment of Melasma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Women at the range of 18 to 50 years old with symmetrical bilateral melasma who signature the letter of satisfaction

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`

Age

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

Gender

Female

Phase

2

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **40**

More than 1 sample in each individual

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

Right face treated with intradermal of tranexamic acid and left face treated with hydroquinon 4%

Randomization (investigator's opinion)

Randomized

Randomization description

Permuted 4 block randomization

Blinding (investigator's opinion)

Double blinded

Blinding description

Value assessment blind about 4 and 10 mg/ml tranexamic acid dose.

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

No. 11, East Kiyanpars

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Ahvaz`

Province

Khuzestan

Postal code

6155964375

Approval date

2018-01-29, 1396/11/09

Ethics committee reference number

IR.AJUMS.REC.1396.1091

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 22

Method of measurement

Melasma area and severity index score

Secondary outcomes

1

Description

patients satisfaction

Timepoint

Measuring of patient satisfaction in 8, 12 and 22 week of trial

Method of measurement

Satisfaction percentage questionnaire

Intervention groups

1

Description

Intervention group 1: Right side face treated with intradermal 4 mg/ml tranexamic acid every other week for 12 weeks.

Category

Treatment - Drugs

2**Description**

Intervention group 2: Right side face treated with intradermal 10 mg/ml tranexamic acid every other week for 12 weeks. Tranexamic acid is a product of Caspian Tamin Pharmaceutical Company in 500 mg/5ml vial.

Category

Treatment - Drugs

3**Description**

Control group: Left side face treated with eldoquin fort 4% cream is a product of ICN company twice a day for 12 weeks.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Dermatology department, Imam hospital,Ahvaz

Full name of responsible person

Maryam Zeynalie

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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

Maryam Zeynalie

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Person responsible for updating data

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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