Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 divded 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

City
Ahvaz´

Province
Khouzestan

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
Street address
Imam khomeini medicinal academic center, Azadegan street
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+98 61 1292 1837
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zeynalie.m@ajums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Mohammad Badavi
Street address
Ground floor, Vice chanceller of Research, Ahvaz Jundishapur University of Medical Sciences, Daneshgahi town, Ahvaz
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Ahvaz
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Postal code
6135715794
Phone
+98 61 3373 8383
Email
zeynalie.m@ajums.ac.ir
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

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Name of organization / entity
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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)

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