Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Jun 2026

A comparative study of effectiveness and side effects between subcutaneous Tranexamic acid injection and Hydroquinon 4% cream in treatment of face melasma in patients referreing to Shohada-e-Tajrish and Loghman-e-Hakim hospitals

Protocol summary

Summary

(1) Main outcome:The goal of this trial is comparative study of effectiveness and side effects between subcutaneous Tranexamic acid injection and Hydroquinon 4% cream in treatment of face melasma in patients between 20-50 years old that referreing to Shohada-e-Tajrish and Loghman-e-Hakim hospitals. This trial is a randomized, not blinded, without placebo and interventional study. (2) Design: Patients divided in to two groups randomly. First group: Injection of subcutaneous Tranexamic acid without dilusion. Second group: Use of Hydroquinon 4% cream at night. (3) Setting and conduct: In every session maximum dose of Tranexamic acid is 1cc and maximum dose of Hydroquinon 4% cream is 1 gr for the whole lesion. Patients follow up is every 4 weeks for 4 times. In this study we use MASI score to compare the effectiveness of treatments. (4) Participants including major eligibility criteria: Inclusion criteria: Every patient between 20-50 years old that do not use any topical treatment for melasma at least 1 month before the trial and have epidermal melasma with wood 's lamp and do not have exclusion criteria. Exclusion criteria: Pregnancy and lactation; Dermal melasma; Using any treatment for melasma during 1 month ago; Using OCP or any hormonal or phototoxic drugs. (5) Intervention: Subcutaneous Tranexamic acid injection and using of Hydroquinon 4% cream (6) Objectives measures (variables): Hyperpigmentation homogenecity; Area involved; Darkness of pigment compared with normal skin

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015110324865N1**
Registration date: **2016-09-17, 1395/06/27**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-09-17, 1395/06/27

Registrant information

Name

Bita Saghi

Name of organization / entity

Shahid Beheshti university of medical science

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2016-07-22, 1395/05/01

Expected recruitment end date

2017-01-20, 1395/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study of effectiveness and side effects between subcutaneous Tranexamic acid injection and Hydroquinon 4% cream in treatment of face melasma in patients referreing to Shohada-e-Tajrish and Loghman-e-Hakim hospitals

Public title
Effectiveness of subcutaneous Tranexamic acid injection and Hydroquinon cream in treatment of melasma
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Every patient between 20-50 years old that do not use any topical treatment for melasma at least 1 month before the trial and have epidermal melasma with wood 's lamp and do not have exclusion criteria. Exclusion criteria: Pregnancy and lactation; Dermal melasma; Using any treatment for melasma during 1 month ago; Using OCP or any hormonal or phototoxic drugs.
Age
From **20 years** old to **50 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **52**
Randomization (investigator's opinion)
Randomized
Randomization description
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
Morality commitee of Shahid Beheshti University of Medical Sciences
Street address
Shahid Beheshti University of Medical Science, Next to Ayatollah Taleghani Hospital, Evin, Tehran
City
Tehran
Postal code
Approval date
2015-12-06, 1394/09/15
Ethics committee reference number
IR.SBMU.RAM.REC.1394.420

Health conditions studied

1

Description of health condition studied
Melasma
ICD-10 code
L81.1
ICD-10 code description
Chloasma

Primary outcomes

1

Description
Hyperpigmentation homogeneity
Timepoint
Before intervention,4 weeks and 8 weeks after begining of the intervention and 4 weeks ater the end of the intervention
Method of measurement
MASI score

2

Description
Area involved
Timepoint
before intervention,4weeks and 8 weeks after begining of the intervention and 4 weeks ater the end of the intervention
Method of measurement
MASI score

3

Description
Darkness of pigment compared with normal skin
Timepoint
before intervention,4weeks and 8 weeks after begining of the intervention and 4 weeks ater the end of the intervention
Method of measurement
MASI score

Secondary outcomes

1

Description
Erythema
Timepoint
4 weeks and 8 weeks after beginning of the intervention and 4 weeks after the end of the intervention
Method of measurement
Asking the patient

2

Description
Irritation
Timepoint
4 weeks and 8 weeks after beginning of the intervention and 4 weeks after the end of the intervention
Method of measurement
asking the patient

3

Description
Dryness
Timepoint
4 weeks and 8 weeks after beginning of the intervention and 4 weeks after the end of the intervention
Method of measurement
Asking the patient

4

Description
Alergic reaction
Timepoint
4 weeks and 8 weeks after beginning of the intervention and 4 weeks after the end of the intervention
Method of measurement
Asking the patient

Intervention groups

1

Description
In the first group: After using of topical anesthesia at the injection site (lidocaine cream 60 minutes before injection), Tranexamic acid ampoule intradermaly is injected into the melasma lesions with 1 cm intervals. The injections is done three times with 4 weeks intervals (weeks 0, 4 and 8) and followed up for 3 months with 4 weeks intervals. Tranexamic acid is available as 5 mL ampoule containing 500 mg of the drug. Maximum dose of Tranexamic acid to the entire affected area is 100 mg(1ml).
Category
Treatment - Drugs

2

Description
In the second group: About the amount of the usage of Hydroquinon 4% cream we use Finger Tip Unit indicator and the maximum dose in every usage is 1 gr. Treatment period is 12 weeks. Assessment of response is every 4 weeks (weeks 4, 8, 12).
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shohada Hospital
Full name of responsible person
Bita Saghi
Street address
Shohada Hospital, Tajrish square, Tehran
City
Tehran

2

Recruitment center
Name of recruitment center
Loghman Hospital
Full name of responsible person
Bita Saghi
Street address
Loghman Hospital, Makhsoos Street, South Karegar Avenue, Tehran
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-Chancellor in Research Affairs of Shahid Beheshti University of Medical Science
Full name of responsible person
Dr. Afshin Zarghi
Street address
Shahid Beheshti University of Medical Science, Next to Ayatollah Taleghani Hospital, Evin, Tehran
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice-Chancellor in Research Affairs of Shahid Beheshti University of Medical Science
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Skin Research Center
Full name of responsible person
Bita Saghi
Position
Dermatology resident
Other areas of specialty/work
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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty