

# 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 homogeneity; 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

Bitra Saghi

###### Name of organization / entity

Shahid Beheshti university of medical science

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2274 1507

###### Email address

zohrehtehranchi@sbmu.ac.ir

##### 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 committee 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 beginning 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 beginning 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 beginning 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**

Allergic 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 intradermally 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**

Bitasaghi

##### **Street address**

Shohada Hospital, Tajrish square, Tehran

##### **City**

Tehran

### 2

#### **Recruitment center**

##### **Name of recruitment center**

Loghman Hospital

##### **Full name of responsible person**

Bitasaghi

##### **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**

Bitra Saghi

**Position**

Dermatology resident

**Other areas of specialty/work****Street address**

Skin Research Center, Shohada Hospital, Tajrish Square, Tehran

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**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

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**Full name of responsible person**

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

Skin Research Center

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**Other areas of specialty/work****Street address**

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Tehran

**Postal code****Phone**

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**Fax****Email****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*