

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### Comparison of the Efficacy of Hydroquinone 2% cream versus Tranexamic Acid Injection in Treatment of Melasema

#### Protocol summary

##### Summary

(1) Objectives, Comparison of the Efficacy of Hydroquinone 2% cream versus Tranexamic Acid Injection in Treatment of Melasema. (2) design ,This trial is a clinical trial, and one side of the patient's face plays the role of control for the intervention on the other side, and the sample size is 37 patients, and it will be done in one dermatology center. (3) Setting and conduct, In this study, for one side of the patient, topical hydroquinone was used at night and on the other side of the tranexamic acid injection by a panel physician. And the patient will be paid for free during monthly intervals and will calculate the severity of the lesions and their recovery rate with the machine in the Moccoche and will record in the relevant information form. During this study, patients will be evaluated for the incidence of side effects and recurrence of the lesion, and the rate of melasma reduction in patients will be documented both subjectively and by the device in the mucocut. (4) Participants including major eligibility criteria, the people with melasma who do not have pregnancy and lactation and who have not used other clarifying compounds during the past 3 months can enter to the study.(5) Interventions. In this study, the concentration of 20 mg/ml of Tranexamic Acid for topical infusion will be used; it will be used by the physician in an intradermal setting at 1 cm intervals in place of melasma. 100 ml insulin is used to inject Nidal. After the local injection, the ice cream compressor will also be used. This process will be performed at intervals of 4 weeks for 3 months. (6) main outcome measures (primary and secondary outcome variables) include melasma and the amount of melanin in the skin, and the secondary variables include the patient's satisfaction subjectively.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017040533244N1**

Registration date: **2017-09-20, 1396/06/29**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-09-20, 1396/06/29

##### Registrant information

###### Name

Mohammad Derayesh

###### Name of organization / entity

Shiraz University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 71 3230 6682

###### Email address

darayesh@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

vice counselor of Research of Shiraz University of Medical Sciences

##### Expected recruitment start date

2016-12-21, 1395/10/01

##### Expected recruitment end date

2017-03-21, 1396/01/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the Efficacy of Hydroquinone 2% cream versus Tranexamic Acid Injection in Treatment of

Melasma

## Public title

Efficacy of Hydroquinone 2% cream versus Tranexamic Acid Injection

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: All patients with melasma Exclusion criteria: Patients treated with steroids; Hydroquinone; Tretinoin; Azaleaic Acid and Kojic Acid; or pregnant; will be excluded. In addition, patients who have taken OCP over the past 12 months and who are taking light-sensitive drugs such as tetracycline; spironolactone; phenytoin and carbamazepine; or coagulation disorders and taking anticoagulant drugs will also be excluded.

## Age

No age limit

## Gender

Both

## Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: 37

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Single blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

SUMS

##### Street address

Shiraz Zand st.

##### City

Shiraz

##### Postal code

7133613769

#### Approval date

2015-09-23, 1394/07/01

#### Ethics committee reference number

IR.SUMS.MED.REC.1396.02

### 2

#### Ethics committee

##### Name of ethics committee

SUMS

##### Street address

shiraz zand st.

##### City

shiraz

##### Postal code

#### Approval date

2017-08-20, 1396/05/29

#### Ethics committee reference number

IR.SUMS.MED.REC.1396.02

## Health conditions studied

### 1

#### Description of health condition studied

Melasma

#### ICD-10 code

#### ICD-10 code description

### 2

#### Description of health condition studied

melasma

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Melasma and Melanin Density in Skin

#### Timepoint

Each 1 month

#### Method of measurement

Analysis with Dermacath

## Secondary outcomes

### 1

#### Description

The Subjective Patient Satisfaction

#### Timepoint

After 3 month

#### Method of measurement

By VAS system

## Intervention groups

### 1

#### Description

In this study, for one side of the patient, topical hydroquinone 2% is used at night.

#### Category

Treatment - Drugs

## 2

### Description

On the other side, the tranexamic acid injection is used by the panel physician, with each side being randomly selected in each patient . During this study, patients will be evaluated for the incidence of side effects and recurrence of the lesion, and the rate of melasma reduction in patients will be documented both subjectively and by the device in the mucocut. In this study, the concentration of 20 mg / ml of Tranxamic Acid for topical infusion will be used; it is used by the physician in an interdermal setting at 1 cm intervals in place of melasma. 100 ml insulin is used to inject Nidal. After the local injection, the ice cream compressor will also be used. This process will be performed at intervals of 4 weeks for 3 months; then patients will follow a monthly follow up for 3 months.

### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Shiraz Shahid Faghihi Hospital

**Full name of responsible person**

Dr.Nasrin Saki

**Street address**

Shiraz Zand st.

**City**

Shiraz

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Deputy of Research and Technology of Shiraz  
University of Medical Sciences

**Full name of responsible person**

Dr.Seied Basir Hashemi

**Street address**

Faghihi hospital , Zand st , Shiraz, Iran

**City**

Shiraz

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Deputy of Research and Technology of Shiraz University  
of Medical Sciences

**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**

Shiraz University of Medical Sciences

**Full name of responsible person**

Dr.Nasrin Saki

**Position**

Dermatologist

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Faghihi hospital ;Zand st ; Shiraz ; Iran

**City**

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+98 7109171180129

**Fax****Email**

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**Web page address**

## Person responsible for scientific inquiries

### Contact

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**Full name of responsible person**

Dr.Nasrin Saki

**Position**

Dermatologist

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Dr.Mohammad Derayesh

**Position**

Dermatology Resident

**Other areas of specialty/work**

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**Postal code****Phone**

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**Fax****Email****Web page address****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*