

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of the efficacy of topical tranexamic acid 5% gel with and without fractional CO laser therapy in treatment of melasma

#### Protocol summary

##### Summary

The study is designed to compare the additive efficacy of fractional CO<sub>2</sub> laser with topical tranexamic acid gel in the treatment of melasma. The study is a randomized, single-blind, unicenter, clinical trial. Inclusion criteria include patients with epidermal and mixed melasma and diseased for at least 6 months. Exclusion criteria include dermal type melasma, oral contraceptive pill consumption since 3 months before enrolment in the study, topical or oral corticosteroid consumption, other pigmentation disorders, history of endocrinopathy disorders, pregnancy, lactation, topical depigmenting medication application in the recent 1 month, oral retinoids or oral and injectable tranexamic acid consumption in the recent 6 months. The patients are selected by convenient sampling from tinea versicolor patients referred to dermatology clinic of Faghihi hospital in Shiraz and 25 patients are enrolled in the study. The patients receive two treatments in both sides of their face by block randomization. In the intervention side which is determined by block randomization, once monthly fractional CO<sub>2</sub> laser is done besides twice daily topical application of tranexamic acid gel and in the control side, only topical tranexamic acid gel is applied twice daily. Primary outcome measure is melanin content measured by Dermacatch instrument and secondary outcome measures are modified Melasma Area and Severity Index (mMASI), investigator global scale and patient global scale.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017080716557N3**

Registration date: **2017-08-13, 1396/05/22**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2017-08-13, 1396/05/22

##### Registrant information

###### Name

Mozhdeh Sepaskhah

###### Name of organization / entity

Shiraz University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 712125239

###### Email address

sepaskhah@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Research council of Shiraz University of Medical Sciences

##### Expected recruitment start date

2017-08-23, 1396/06/01

##### Expected recruitment end date

2017-10-22, 1396/07/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the efficacy of topical tranexamic acid 5% gel with and without fractional CO laser therapy in treatment of melasma

##### Public title

Effect of fractional CO<sub>2</sub> laser and Tranexamic acid gel in the treatment of melasma

##### Purpose

Treatment

### **Inclusion/Exclusion criteria**

Inclusion criteria: Patients with epidermal and mixed melasma; diseased for at least 6 months  
Exclusion criteria: Dermal type melasma; Oral contraceptive pill consumption since 3 months before enrolment in the study; Topical or oral corticosteroid consumption; Other pigmentation disorders; History of endocrinopathy disorders; Pregnancy; Lactation; Topical depigmenting medication application in the recent 1 month; Oral retinoids or oral and injectable tranexamic acid consumption in the recent 6 months

### **Age**

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

### **Gender**

Both

### **Phase**

N/A

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **25**

### **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**

Ethics committee of Shiraz University of Medical Sciences

##### **Street address**

Shiraz University of Medical Sciences, Zand St., Shiraz. Iran

##### **City**

Shiraz

##### **Postal code**

#### **Approval date**

2017-06-14, 1396/03/24

#### **Ethics committee reference number**

IR.SUMS.MED.REC.1396.48

## **Health conditions studied**

### **1**

#### **Description of health condition studied**

Melasma

#### **ICD-10 code**

L81.1

#### **ICD-10 code description**

Chloasma

## **Primary outcomes**

### **1**

#### **Description**

Melanin content

#### **Timepoint**

months 0, 1, 2, 3

#### **Method of measurement**

A number measured by Dermacatch

## **Secondary outcomes**

### **1**

#### **Description**

modified Melasma Area and Severity Index (mMASI)

#### **Timepoint**

months 0, 1, 2, 3

#### **Method of measurement**

Scoring of color and extent of lesions and calculation based on the formula

### **2**

#### **Description**

Investigator global scale

#### **Timepoint**

months 0, 1, 2, 3

#### **Method of measurement**

Investigator's assessment of global severity of the lesion

### **3**

#### **Description**

Patient global scale

#### **Timepoint**

months 0, 1, 2, 3

#### **Method of measurement**

Patient's assessment of global severity of the lesion

## **Intervention groups**

### **1**

#### **Description**

Intervention side: Once monthly fractional CO2 laser (DSE, South Korea), 169 dots per pulse, energy 12mj, 1-2 pass for 3 sessions is done besides twice daily topical application of tranexamic acid 5% gel for 3 months

#### **Category**

Treatment - Surgery

## 2

### Description

Control side: Only topical tranexamic acid 5% gel is applied twice daily for 3 months.

### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Dermatology clinic, Shahid Faghihi hospital

##### Full name of responsible person

Leila sadat Khamesi

##### Street address

Dermatology clinic, Faghihi hospital, Zand St., Shiraz, Iran

##### City

Shiraz

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Research Council of Shiraz University of Medical Sciences

##### Full name of responsible person

Dr. Seyed Basir Hashemi

##### Street address

Research Council, Shiraz University of Medical Sciences, Zand St., Shiraz, Iran

##### City

Shiraz

##### Grant name

##### Grant code / Reference number

93-01-01-8716

##### Is the source of funding the same sponsor organization/entity?

Yes

##### Title of funding source

Research Council 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

Leila sadat Khamesi

#### Position

Resident

#### Other areas of specialty/work

#### Street address

Dermatology clinic, Faghihi hospital, Zand St., Shiraz, Iran

#### City

Shiraz

#### Postal code

7134844119

#### Phone

+98 71 3231 9049

#### Fax

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#### Email

l.khamesi@gmail.com

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Shiraz University of Medical Sciences

#### Full name of responsible person

Mozhdeh Sepaskhah

#### Position

Fellowship

#### Other areas of specialty/work

#### Street address

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sepaskhah@sums.ac.ir

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## Person responsible for updating data

### Contact

#### Name of organization / entity

Shiraz University of Medical Sciences

#### Full name of responsible person

Mozhdeh Sepaskhah

#### Position

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#### Other areas of specialty/work

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**Email**

sepaskhah@sums.ac.ir

**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*