

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Jun 2026

### Comparison of efficacy and safety of topical Tranexamic Acid with and without using non-ablative fractional Erbium glass in patients with melasma referring to Razi Hospital laser 1540nm for treatment of melasma in patients referred to Razi hospital

#### Protocol summary

##### Summary

Melasma is a common problem, treatment of melasma is a real challenge due to its frequent recurrence and aggravation even during or after treatment. no single treatment has been proven to be the most effective. therefore, combination treatment using several possible modalities has been preferred. in this study we analyse efficacy of topical tranexamic acid with and without erbium glass laser 1540nm in patients with melasma. an important inclusion criteria is symmetric melasma. group 1 uses topical tranexamic acid and group 2 in addition of use topical tranexamic acid, laser monthly. every half of each face using table of random number place in a group. A blind dermatologist assesses patient using Melasma Area and Severity Index and his clinical assess, also patients' satisfaction.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016011626047N1**  
Registration date: **2016-04-24, 1395/02/05**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-04-24, 1395/02/05

##### Registrant information

##### Name

Zahra Shadlou

##### Name of organization / entity

Tehran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8898 0513

##### Email address

zshadlou@razi.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Tehran University of Medical Science

##### Expected recruitment start date

2016-02-20, 1394/12/01

##### Expected recruitment end date

2016-09-20, 1395/06/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of efficacy and safety of topical Tranexamic Acid with and without using non-ablative fractional Erbium glass in patients with melasma referring to Razi Hospital laser 1540nm for treatment of melasma in patients referred to Razi hospital

##### Public title

The efficacy of topical Tranexamic Acid with and without using laser laser for treatment of melasma

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

inclusion criteria: 18-65 years; symmetrical melasma in both half of the face; patients' satisfaction; skin type 1-5  
exclusion criteria: use hydroquinone, topical and oral

retinoid, topical steroid, alfa hydroxy acids and other drugs effect on pigmentation in past 4 weeks; use Oral Conterseptive Pill; chemical peeling,microderm abration, dermabratin or laser in past 3 months; history of past sensitivity to tranexamic acid; pregnancy; lactation; history ischemic or hemorrhagic events of coronal or cerebral arteries

#### Age

From **18 years** old to **65 years** old

#### Gender

Both

#### Phase

3

#### 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 Tehran University of Medical Science

##### Street address

Room105, 5th floor, Central building Tehran  
University of Medical Science, GHods avenue, Keshvarz  
boulevard, Tehran

##### City

Tehran

##### Postal code

1417653761

#### Approval date

2016-02-07, 1394/11/18

#### Ethics committee reference number

IR.TUMS.REC. 1394.1905

## Health conditions studied

### 1

#### Description of health condition studied

melasma

#### ICD-10 code

L81.1

#### ICD-10 code description

Chloasma

## Primary outcomes

### 1

#### Description

pigmantation

#### Timepoint

before intervention,at the end of intervention,1 mouth  
and 3 mouths after end of intervention

#### Method of measurement

modified Melasma Area and Severity Index(mMASI)  
score,digital photography,patient  
satisfaction(questionnaire),physician assessment

## Secondary outcomes

### 1

#### Description

topical adwers effects

#### Timepoint

every month in intervention period and end of  
intervention

#### Method of measurement

questionnaire and observation

## Intervention groups

### 1

#### Description

intervention group: topical tranexamic acid 5% in cold  
cream 2 times in a day withfractional erbium glass  
1540nm(Sturlux) monthly

#### Category

Other

### 2

#### Description

control group: topical tranexamic acid 5% in cold cream  
2 times in a day

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Razi Hospital

##### Full name of responsible person

Dr Zahra Shadlou

##### Street address

Razi Hospital, Vahdat eslami Square, Vahdat eslami  
Street

**City**  
Tehran

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**  
Vice chancellor for research, Tehran University of Medical Science

**Full name of responsible person**  
Dr Masud Yunesian

**Street address**  
Central building of Tehran University of Medical Science, Keshavarz Boulevard, 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 for research, Tehran 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**  
Tehran University of Medical Science

**Full name of responsible person**  
Dr Zahra Shadlou

**Position**  
Skin disease Resident

**Other areas of specialty/work**

**Street address**  
Razi Hospital

**City**  
Tehran

**Postal code**  
1199663911

**Phone**  
+98 21 5563 0669

**Fax**

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zshadlou@razi.tums.ac.ir; dr.z.shadlou@gmail.com

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Tehran University of Medical Science

**Full name of responsible person**  
Dr Amir houshang Ehsani

**Position**  
Associate Professor

**Other areas of specialty/work**

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Razi Hospital

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1199663911

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ehsanih@sina.tums.ac.ir

**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Tehran University of Medical Science

**Full name of responsible person**  
Dr Zahra Shadlou

**Position**  
Skin disease Resident

**Other areas of specialty/work**

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zshadlou@razi.tums.ac.ir; dr.z.shadlou@gmail.com

**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*