

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of the efficacy of Fractional Erbium: YAG laser and topical hydroquinone 4% versus intradermal tranexamic acid and topical hydroquinone 4% in treatment of resistant melasma

#### Protocol summary

##### Study aim

Determination and comparison of mean MASI score in two groups at baseline and one month, two months, three months after start treatment and three months after end of treatment.

##### Design

Clinical trial without control group with parallel, blinded, randomized groups individually

##### Settings and conduct

27 female patients with refractory melasma presenting to the Alzahra Hospital dermatology Clinic and Sedigheh Tahere Center randomly selected (Half face in the form of a group). These patients are treated with Erbium Yag laser with twice daily use of 4% Hydroquinone cream on one side of face and tranexamic acid by intradermal injection in melasma areas intervals for three months with twice daily use of 4% hydroquinone cream on the other hand the face will be cured within three months.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Female patients with refractory melasma with a range of 20-50 years. Having informed consent to participate in the study. No pregnancy or lactation. No systemic diseases.

##### Intervention groups

27 female patients with refractory melasma with skin type ranging from 2 to 4 randomly selected (Half face in the form of a group). Severity of melasma lesions based on color, size, and clinical presentation seen by a specialist physician and recorded by photographic (imaging) and dermoscopy techniques. These patients were treated with Erbium Yag laser every two weeks for six sessions (Weeks 0, 2, 4, 6, 8 and 10) With twice daily use of 4% Hydroquinone Cream on one side of face and tranexamic acid by intradermal injection of 1 ml at a concentration of 100 mg / ml in melasma areas at one centimeter intervals for three months (weeks 0, 4, 8 and 12) with twice daily use of 4% hydroquinone cream on

the other hand, the face will be cured within three months.

##### Main outcome variables

Better effects of combination treatments and lower cost and less recurrence

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20191011045057N1**

Registration date: **2020-02-05, 1398/11/16**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-02-05, 1398/11/16**

Update count: **0**

##### Registration date

2020-02-05, 1398/11/16

##### Registrant information

##### Name

Bahareh Bahrami

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3230 7101

##### Email address

bahar\_bahrami45@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-09-22, 1398/06/31

##### Expected recruitment end date

2020-04-17, 1399/01/29

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of the efficacy of Fractional Erbium: YAG laser and topical hydroquinone 4% versus intradermal tranexamic acid and topical hydroquinone 4% in treatment of resistant melasma

**Public title**

Laser in treatment of resistant melasma, Intradermal tranexamic acid in treatment of resistant melasma

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Female patients with melasma with age ranging from 20 to 50 years Having informed consent to participate in the study No pregnancy or lactation No systemic diseases

**Exclusion criteria:**

Female patients with melasma younger than 20 years and over 50 years Lack of informed consent to participate in the study Pregnancy or lactation Systemic diseases

**Age**

From **20 years** old to **50 years** old

**Gender**

Female

**Phase**

2

**Groups that have been masked**

- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **27**

More than 1 sample in each individual

Number of samples in each individual: **2**

Half face in the form of a group

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Block randomization - Individual randomization unit - SPSS statistical software is used for randomization.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

Those responsible for evaluating the data are blind to the results. These people are unaware of the treatment on each side of the patient's face, so they are blind to this assessment.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Isfahan University of Medical Sciences

**Street address**

Shahid Keshvari Highway, Sofe Boulevard, Alzahra Medical Center

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174675731

**Approval date**

2019-09-23, 1398/07/01

**Ethics committee reference number**

IR.MUI.MED.REC.1398.339

**Health conditions studied****1****Description of health condition studied**

Melasma

**ICD-10 code**

L81.1

**ICD-10 code description**

Chloasma

**Primary outcomes****1****Description**

MASI score

**Timepoint**

Get started, one month later, two month later, three months later, three months after the end of treatment

**Method of measurement**

check list and examination

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: Laser therapy with topical treatment (4% hydroquinone cream) for the treatment of refractory melasma in one side of a person

**Category**

Treatment - Devices

## 2

### Description

Intervention group: Intranasal injection of tzanexamic acid plus topical treatment (4% hydroquinone cream) to treat refractory melasma on the other side of the same face

### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Isfahan Alzahra Hospital

##### Full name of responsible person

Bahareh Bahrami

##### Street address

Shahid Keshvari Highway, Sofe Boulevard, Alzahra Medical Center

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8174675731

##### Phone

+98 31 3620 2020

##### Email

bahar\_bahrami45@yahoo.com

### 2

#### Recruitment center

##### Name of recruitment center

Sedigheh Tahereh Clinic of Isfahan

##### Full name of responsible person

Bahareh Bahrami

##### Street address

Islamic Republic Square, Khorram St, Sadegh Tahereh Research Complex

##### City

Isfahan

##### Province

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##### Postal code

8156885193

##### Phone

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##### Email

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## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Esfahan University of Medical Sciences

##### Full name of responsible person

shaghahegh hagh joy javanmard

##### Street address

Vice chancellor for research and technology, University Building 4, Isfahan University of Medical Sciences, Hezar Jarib Ave., Isfahan, Iran

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8174673461

##### Phone

+98 31 3792 3060

##### Email

research@mui.ac.ir

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Esfahan University of Medical Sciences

##### Proportion provided by this source

100

##### Public or private sector

Public

##### Domestic or foreign origin

Domestic

##### Category of foreign source of funding

*empty*

##### Country of origin

##### Type of organization providing the funding

Academic

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Esfahan University of Medical Sciences

##### Full name of responsible person

Bahareh Bahrami

##### Position

Resident

##### Latest degree

Medical doctor

##### Other areas of specialty/work

Dermatology

##### Street address

Shahid Keshvari Highway, Sofe Boulevard, Alzahra Medical Center

##### City

Isfahan

##### Province

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##### Postal code

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##### Phone

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##### Email

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Fateme Mokhtari

**Position**

Associate Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dermatology

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Bahareh Bahrami

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dermatology

**Street address**

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**Phone**

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**Email**

bahar\_bahrami45@yahoo.com

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

Due to the project going on, I still have no decision.

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Not applicable

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available