

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 May 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

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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

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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

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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

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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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Fateme Mokhtari

Position

Associate Professor

Latest degree

Specialist

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Person responsible for updating data

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Position

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Latest degree

Medical doctor

Other areas of specialty/work

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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