Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of the efficacy of Fractional Erbium: YAG laser and topical hyroquinone 4% versus intradermal tranexamic acid and topical hyroquinone 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 hyroquinone 4% versus intradermal tranexamic acid and topical hyroquinone 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
Isfehan
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
Isfehan
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
Isfehan
Postal code
8156885193
Phone
+98 31 3335 9696
Email
bahar_bahrami45@yahoo.com

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
Isfehan
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
Isfehan
Postal code
8174675731
Phone
+98 31 3620 2020
Email
bahar_bahrami45@yahoo.com

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

Street address
Shahid Keshvari Highway, Sofe Boulevard, Alzahra Medical Center

City
Isfahan

Province
Isfehan

Postal code
8174675731

Phone
+98 31 3620 2020

Email
f_mokhtari2004@yahoo.com

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
Shahid Keshvari Highway, Sofe Boulevard, Alzahra Medical Center

City
Isfahan

Province
Isfehan

Postal code
8174675731

Phone
+98 31 3620 2020

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