

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of Nd-Yag fractional 1064 laser therapy with tranexamic acid mesotherapy efficacy versus Nd-Yag fractional 1064 laser therapy with oral tranexamic acid in patients suffering melasma.

Protocol summary

Study aim

The aim of this study is to compare the treatment of Nd-Yag fractional 1064 laser with tranexamic acid mesotherapy to Nd-Yag fractional 1064 laser therapy with oral tranexamic acid.

Design

In this study, 34 patients were randomly divided into two equal groups A and B. In order to randomization, a box of 34 pre-filled envelopes which containing A or B code is considered for each patient. Group A received Nd-YAG-Fractional 1064 lasers with tranexamic acid mesotherapy and in group B, the same laser with oral tranexamic acid (1 cap 250 mg every 8 hours for 3 months) was used. Laser therapy consists of 6 sessions at intervals every 2 weeks. Finally, 40 participants (20 people in each group) were included in this study, which is a Phase 3 clinical trial, due to the possible withdrawal of the subjects from the study and follow-up.

Settings and conduct

this double-blind, researcher and analyzer, interventional study was conducted on patients with melasma referring to the Dermatology Clinic of Rasool-Akram hospital.

Participants/Inclusion and exclusion criteria

The inclusion criteria are women suffered melasma with aged 18-50 and I-IV Fitz Patrick skin type and without any diseases associated with tranexamic acid. the exclusion criteria are the incidence of any side effects associated with treatment or the patient's reluctance to continue treatment.

Intervention groups

Nd-Yag-Fractional 1064 laser therapy with tranexamic acid microinjection was done for the first group and the second group treated with the same laser and oral tranexamic acid.

Main outcome variables

The degree of clarification and improvement of melasma lesions; satisfaction of patients; tolerability;

complications of treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140624018210N9**

Registration date: **2019-04-13, 1398/01/24**

Registration timing: **registered_while_recruiting**

Last update: **2019-04-13, 1398/01/24**

Update count: **0**

Registration date

2019-04-13, 1398/01/24

Registrant information

Name

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Name of organization / entity

Iran University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-22, 1397/04/01

Expected recruitment end date

2019-09-21, 1398/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of Nd-Yag fractional 1064 laser therapy with tranexamic acid mesotherapy efficacy versus Nd-Yag fractional 1064 laser therapy with oral tranexamic acid in patients suffering melasma.

Public title
Comparison of Nd-Yag fractional 1064 laser therapy with tranexamic acid mesotherapy efficacy versus Nd-Yag fractional 1064 laser therapy with oral tranexamic acid in patients suffering melasma.

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
patients should have the classical clinical features of melasma. skin type of patients should be I to IV. patients age should be between 18 to 50.
Exclusion criteria:

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

Gender
Female

Phase
3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **40**
More than 1 sample in each individual
Number of samples in each individual: **20**
although 34 participants were estimated for this study, we have considered 40 participants because of the probably missing data. then 20 patients suffered from melasma, were entered in each group.

Randomization (investigator's opinion)
Randomized

Randomization description
patients were entered into each treatment group by computerized random selection with 1:1 ratio. each patient will choose an envelope from a box filled with 60 closed envelope which contains A or B code. (A --> first method and B--> second method)

Blinding (investigator's opinion)
Double blinded

Blinding description
in this double-blind study, unlike the first researcher, second researcher, and analyzer just have access to A and B code. thus they do not know about the exact treatment.

Placebo
Not used

Assignment
Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Niyayesh Ave., Sattar Khan Blvd.

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Province

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1445613131

Approval date

2018-06-11, 1397/03/21

Ethics committee reference number

IR.IUMS.FMD.REC 1396.9511166001

Health conditions studied

1

Description of health condition studied

melasma

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Brightening and improving the appearance of melasma by MASI score

Timepoint

Before the begin of the intervention and then 2, 4, 6, 8, 10, 12 weeks after the treatment in the studied groups

Method of measurement

The device used is Visioface, a scale used in study is melasma area severity index, and a questionnaire on the patient's healing process has also been used.

Secondary outcomes

1

Description

side effect of treatment , tolerability , satisfaction

Timepoint

2, 4, 6, 8, 10, 12, 16 weeks after each treatment stage

Method of measurement

by questionnaire

Intervention groups

1

Description

Intervention group:

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasoul-e-Akram Hospital

Full name of responsible person

Elham behrangi

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Rasoule-Akram Hospital , Niyayesh Ave. , Starkhan Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

Deputy of Research of Iran University of Medical Sciences

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Grant name

Grant code / Reference number

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

No

Title of funding source

Iran Univcrity 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

Iran University of Medical Sciences

Full name of responsible person

Elham behrangi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

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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

there is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available