

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Assessing the effectiveness, safety and patient satisfaction of intradermal tranxamic acid injection in comparison with fractional Q-Switch Nd-yag laser for melasma treatment

Protocol summary

Study aim

Evaluation of the efficacy of intra-dermal tranxamic acid injection in comparison with Q switch Nd-YAG fractional laser in patients referred to the Clinic of skin and Stem Cell Research Center

Design

Two arm parallel group randomised trial with two intervention groups and sample size includes 28 patients randomization is simple with use of randomization numbers table.

Settings and conduct

This study was conducted as a randomized trial. A total of 28 patients who will visit for melasma in the skin and Stem Cell Research Center The aim of this study was to investigate the effect of two treatment groups consist of laser fractional Q-switched on a monthly basis for up to four sessions and intra-lesional injections of tranxamic acid for 12 weeks.

Participants/Inclusion and exclusion criteria

inclusion criteria: women over the age of 18; moderate to severe melasma exclusion criteria: pregnancy; lactation; patients who have received contraceptive drugs in the last 12 months; Patients with hemorrhagic or anticoagulant abnormalities; receiving another treatment for melasma at the same time and none of the patients should receive topical treatment for melasma for example hydroquinone one month before treatment.

Intervention groups

patients in group of intradermal tranxamic acid injection patients in Q switch ND-YAG Fractional laser

Main outcome variables

Melanin index, skin lightening, Modified MASI score, patient satisfaction, VAS score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180418039349N1**

Registration date: **2018-06-27, 1397/04/06**

Registration timing: **registered_while_recruiting**

Last update: **2018-06-27, 1397/04/06**

Update count: **0**

Registration date

2018-06-27, 1397/04/06

Registrant information

Name

Nahid Nikkhah

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2221 5558

Email address

nnikkhah@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-22, 1397/03/01

Expected recruitment end date

2018-11-22, 1397/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessing the effectiveness, safety and patient

satisfaction of intradermal tranxamic acid injection in comparison with fractional Q-Switch Nd-yag laser for melasma treatment

Public title
comparison of efficacy of intradermal tranxamic acid injection with fractional Q-Switch Nd-yag laser for melasma treatment

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
women over the age of 18 moderate to severe melasma
Exclusion criteria:
pregnancy lactation patients who have received contraceptive drugs in the last 12 months Patients with hemorrhagic or anticoagulant abnormalities anticoagulant drug using receiving another treatment for melasma at the same time receive topical treatment for melasma for example hydroquinone one month before treatment.

Age
From **18 years** old

Gender
Female

Phase
3

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **28**

Randomization (investigator's opinion)
Randomized

Randomization description
Using simple randomization Randomization Tool: Random Numbers table

Blinding (investigator's opinion)
Not blinded

Blinding description
Two blind dermatologists will give a score to patients graphies

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 Sciences
Street address
Tehran University of Medical Sciences, Enghelab

Street,Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1937957511

Approval date
2018-02-27, 1396/12/08

Ethics committee reference number
IR.TUMS.VCR.REC.1396.4672

Health conditions studied

1

Description of health condition studied

melasma

ICD-10 code

L81.1

ICD-10 code description

Chloasma

Primary outcomes

1

Description

Melanin index

Timepoint

before treatment session 8,12. three moth after treatment

Method of measurement

multi probe adaptor

2

Description

skin lightening

Timepoint

before treatment session 8,12. three moth after treatment

Method of measurement

colorimeter

3

Description

Modified MASI score

Timepoint

before treatment session 4,8,12. three moth after treatment

Method of measurement

clinically by the physician. face is divided into four parts: forehead, right malar, left malar and chin , and the degree of severity of melasma is measured based on three criteria. The percentage of area (from zero to six points) and the degree of darkness are also categorized from zero to four points.

4

Description

patient satisfaction

Timepoint

in the end of study

Method of measurement

The patient's own assessment of the improvement of melasma is based on four points. Exercise: Improvement of more than 75% / fine: 75-51% Fairly good: 50-26% / Slight: 25-0%

5

Description

graphy

Timepoint

before treatment session 4,8,12. three moth after treatment

Method of measurement

visiofase

Secondary outcomes

empty

Intervention groups

1

Description

In the group treated with tranxamic acid: Prior to treatment, local anesthetic treatment, a 2.5% lidocaine hydrochloride plus 2.5% prilocaine for 20 to 20 minutes will be applied on site. for injection an insulin syringe 30 Gage will be used Injections will be done at intervals of 1 cm at a volume of 0.05 cc at each point , at concentrations of 4 mg per cc , weekly for 12 weeks in each area.

Category

Treatment - Drugs

2

Description

Intervention group: In the laser treatment group, forty-five to sixty minutes prior to treatment local anesthesia (a combination of 2.5% lidocaine and 2.5% prilocaine) will be applied on face to protect the eyes from the laser , eye shield is applied to the eye, and single-pulse laser with these specifications is done for the patients. Lasers are performed at intervals of four sessions for patients. Low fluence fractional Q-switch Nd yag laser: fluence: 1.3j/cm² – energy: 500- spot size: 7mm- frequency: 5Hz

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinic of Skin and Stem Cell Research Center

Full name of responsible person

Nahid Nikkhah

Street address

No4, Mayam Alley, South Kamraniyeh Street, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1937957511

Phone

+98 21 2221 5558

Email

nahid_nikkhah@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Skin and Stem Cell Research Center

Full name of responsible person

Dr Mohammad Ali Nilforooshzadeh

Street address

No4, Mayam Alley, South Kamraniyeh Street, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1937957511

Phone

+98 21 2221 5558

Email

nahid_nikkhah@yahoo.com

Grant name

Grant code / Reference number

123700016

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

Yes

Title of funding source

Skin and Stem Cell Research Center

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

Tehran University of Medical Sciences

Full name of responsible person

Nahid Nikkhah

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

Street address

No4, Mayam Alley, South Kamraniyeh Street, Tehran, Iran

City

tehran

Province

Tehran

Postal code

1937957511

Phone

+98 21 2221 5558

Email

nahid_nikkah@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Nilforoushzadeh

Position

Professor of Tehran Univesity

Latest degree

Specialist

Other areas of specialty/work

Dermatology

Street address

No4, Mayam Alley, South Kamraniyeh Street, Tehran, Iran

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Province

Tehran

Postal code

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Phone

+98 21 2221 5558

Email

nilforoosh@sina.tums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Nahid Nikkhah

Position

assistant professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

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nahid_nikkah@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All of the above is publicly available, Except for cases where patients are identified

When the data will become available and for how long

Start the access period 4 months after printing the results

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

This data will be provided to researchers only for the purpose of allowing future studies and planning of future studies, In the case of direct use of data in future studies, the Center's intellectual property rights should be maintained

From where data/document is obtainable

Secretariat of the skin and Stem Cell Research Center
02122215558

What processes are involved for a request to access data/document

In order to access the patients' data, coordination with Mrs. Mahmoodbeig should be carried out and a letter asking for access to the data be delivered to them, so that, after coordinating with the head of the research center, this work is feasible

Comments

