Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Assessing the effectiveness, safety and patient satisfaction of intradermal tranxamic acid injection in comparision 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 paients in Q switch ND-YAG Fractional laser

Main outcome variables
Melanin index, skin lightening, Modified MASI score, patient satisffaction, 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

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Iran (Islamic Republic of)

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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 comparision with fractional Q-Switch Nd-yag laser for melasma treatment

Public title
comparision 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 dug 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
clinicaly 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 satisffaction
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 anesthetia (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- frequncy:5Htz
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
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Tehran
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nahid_nickhah@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
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Email
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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

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Person responsible for scientific inquiries

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Other areas of specialty/work
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Person responsible for updating data

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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