Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison between the efficacy of multiple microinjections of tranexamic acid (100 mg/ml) with microneedling and topical tranexamic acid (100 mg/ml) in the treatment of melasma in patients with symmetrical face melasma

Protocol summary

Study aim
Comparison of the effectiveness of tranexamic acid administration by intradermal injection with microneedling plus topical tranexamic acid in the treatment of melasma

Design
This clinical trial without blinding in phase three studies will be performed on 27 patients in 2 groups of 13 and 14 people. The patients are numbered and the numbers are divided according to the table of random numbers.

Settings and conduct
Patients referred to the dermatology clinic of Isfahan medical university with inclusion criteria after randomization are divided into two groups. After 12 weeks of treatment, patients are photographed again and visited by a neutral physician, and MASI scoring is performed. This study will be performed without blinding.

Participants/Inclusion and exclusion criteria
Patients with symmetrical melasma on the cheeks with Fitzpatrick II-IV skin type will be included in the study. Patients with contraindications to tranexamic acid or diseases that affect the patient's treatment will not be included in the study.

Intervention groups
The first intervention group consisted of 13 patients who will undergo microneedling on the right side of the face and then tranexamic acid will be applied topically. On the left side of the face Intradermal injection of tranexamic solution will be performed at intervals of 1 cm. Drugs will be administered at intervals of one month to 3 times. The second intervention group includes 14 patients who will undergo microneedling on the left side of the face and then tranexamic acid will be applied topically. On the right side of the face Intradermal injection of tranexamic solution will be performed at intervals of 1 cm. Medications will be prescribed up to 3 times a month.

Main outcome variables
MASI scoring for photographs of melasma patients

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201205049603N1**
Registration date: **2021-02-08, 1399/11/20**
Registration timing: **registered_while_recruiting**

Last update: **2021-02-08, 1399/11/20**
Update count: **0**

Registration date
2021-02-08, 1399/11/20

Registrant information

Name
Maryam Alizadeh

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 31 5554 5032

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-11-30, 1399/09/10

Expected recruitment end date
2021-04-30, 1400/02/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between the efficacy of multiple microinjections of tranexamic acid (100 mg/ml) with microneedling and topical tranexamic acid (100 mg/ml) in the treatment of melasma in patients with symmetrical face melasma

Public title

Comparison of the effect of intradermal injection of tranexamic acid versus microneedling plus topical tranexamic acid in the treatment of patients with melasma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having Fitzpatrick II-IV skin type with symmetrical melasma diagnosed by a dermatologist Patient willingness to participate in the study

Exclusion criteria:

Patients receiving OCP, anticonvulsants, antidepressants, and thyroid medications over the past 12 months Existence of coagulation disorder or anticoagulant use in the patient Patient sensitivity to the studied compounds Existence of active herpes, facial warts or active dermatosis Pregnancy or lactation

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **27**

More than 1 sample in each individual

Number of samples in each individual: **2**

In each person, the right side of the cheek will be considered as an example and the left side of the cheek as another example.

Randomization (investigator's opinion)

Randomized

Randomization description

Patients who met the inclusion criteria will randomly divided into two groups using random allocation software, this software creates a random sequence by blocking method. Each patient participating in the study will receive a unique code, and the person performing the randomization with the software will not be informed of any further actions and interventions. After assigning the code the patients will be divided into two groups. The first intervention group will undergo microneedling on the right side of the face and then tranexamic acid will be applied topically. On the left side of the face, an Intradermal injection of the tranexamic solution will be performed. The second intervention group will undergo microneedling on the left side of the face and then tranexamic acid will be applied topically. On the right side of the face, Intradermal injection of the tranexamic solution will be performed

Blinding (investigator's opinion)

Not blinded

Blinding description

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

Soffeh Blvd

City

Isfahan

Province

Isfehan

Postal code

8174675731

Approval date

2020-11-22, 1399/09/02

Ethics committee reference number

IR.MUI.MED.REC.1399.743

Health conditions studied

1

Description of health condition studied

melasma

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

MASI scoring for photographs of patients with melasma

Timepoint

Before the start of the study and 4 weeks after the end of treatment

Method of measurement

MASI score for photography

Secondary outcomes

1

Description
Patient satisfaction with treatment
Timepoint
4 weeks after treatment
Method of measurement
questionnaire

Intervention groups

1

Description
Intervention group 1: includes 13 patients whose right side of the face is 100 mg / ml tranexamic acid solution is topically apllied on the skin surface then microneedling (inopen made in USA) is used and the left side of the face is injected 100 mg / ml sterile transaxamic solution Injectable (Daru Pakhsh Company) is done in sections with a distance of 1 cm of tranexamic acid. Medications will be prescribed up to 3 times a month.
Category
Treatment - Drugs

2

Description
Intervention group 2: includes 13 patients whose left side of the face is 100 mg / ml tranexamic acid solution is evenly distributed on the skin surface and immediately microneedling (inopen made in USA) is used and the right side of the face is injected 100 mg / ml sterile transaxamic solution Injectable (Daru Pakhsh Company) is done in sections with a distance of 1 cm of tranexamic acid. Medications will be prescribed up to 3 times a month.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Dermatology Clinic of Isfahan University of Medical Sciences
Full name of responsible person
Maryam Alizadeh
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Shaghayegh Haghjoo Javanmard
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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
Maryam Alizadeh
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
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Person responsible for scientific inquiries

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Position
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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
The primary outcome data will be shared.
When the data will become available and for how long
Start the access period is 6 months after publishing the results.
To whom data/document is available
Academic researchers
Under which criteria data/document could be used
The request can be made by e-mail to the corresponding author
From where data/document is obtainable
It can be done by e-mail to maryam.alizadeh87@gmail.com
What processes are involved for a request to access data/document
Once the applicant has provided details of their ongoing project within one month from the time of application data will be available.
Comments