

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jul 2026

Comparison between microneedling plus topical tranexamic acid and microneedling in patients with macular amyloidosis

Protocol summary

Study aim

Comparison between microneedling plus topical tranexamic acid and microneedling in patients with macular amyloidosis referred to dermatology clinic of Shohada-e-Tajrish Hospital and Loghman-Hakim Hospital

Design

Clinical trial with control group, with parallel groups, single-blind, randomized, phase 3 on 22 patients. Excel software (randbetween function) was used for randomization.

Settings and conduct

This survey will be conducted in Shohadaye Tajrish Hospital and Loghman Hakim Hospital. 22 macular amyloidosis patients will randomly divided to microneedling and tranexamic acid plus microneedling group.

Participants/Inclusion and exclusion criteria

1.Age 18-60 2.Confirming the diagnosis of macular amyloidosis by a dermatologist 3.bilateral macular amyloidosis on trunk and extremities 4.Patients with skin type 2_4 Fitzpatrick 5.Filling out the informed consent form

Intervention groups

Tranexamic acid and microneedling group: 4 sessions of microneedling with topical tranexamic acid every two weeks microneedling group: 4 sessions of microneedling every two weeks

Main outcome variables

skin pigmentation and its pattern

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220101053588N1**

Registration date: **2022-01-24, 1400/11/04**

Registration timing: **registered_while_recruiting**

Last update: **2022-01-24, 1400/11/04**

Update count: **0**

Registration date

2022-01-24, 1400/11/04

Registrant information

Name

Shima Moslemi Haghighi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 25719

Email address

mhaghighishima@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-12, 1400/10/22

Expected recruitment end date

2022-09-22, 1401/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between microneedling plus topical tranexamic acid and microneedling in patients with macular amyloidosis

Public title

Comparison between microneedling plus topical tranexamic acid and microneedling in patients with macular amyloidosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18-60 Confirming the diagnosis of macular amyloidosis by a dermatologist bilateral macular amyloidosis on trunk and extremities Patients with skin type 2, 4 Fitzpatrick Filling out the informed consent form

Exclusion criteria:

Pregnancy and lactation Past history of keloid formation Presence of active acne on site of macular amyloidosis Other skin disorders Hypersensitivity to lidocaine Application of other topical medications in the past month

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **22**

Randomization (investigator's opinion)

Randomized

Randomization description

One of the randomization methods is using the RANDBETWEEN function in Excel. This function allows us to generate random numbers. To generate a random number in this study with a sample size of 22, between the two numbers 1 and 0, the function = (0,1) Randbetween is used. This function creates a column of random numbers from 0 to 1. The rand () function sets the numbers with equal probability in this selection interval. The chance of selecting any number in this interval is equal to the other numbers. This means that the treatment on the left or right side of the back or arms of each person is assigned to enter one of two treatments (doing treatment / not doing treatment). These data are 22 people that are randomly assigned to the numbers 0 and 1. In total, people with the number 1 receive treatment on the right side and people with the number 0 receive treatment on the left side of their body. No Right=1, left=0 1 1 2 0 3 1 4 0 5 0 6 1 7 0 8 0 9 1 10 0 11 1 12 1 13 0 14 0 15 1 16 1 17 1 18 0 19 0 20 1 21 1 22 0

Blinding (investigator's opinion)

Single blinded

Blinding description

The method of one-sided blinding in this study will be that the statistical analyst is unaware of the exposure received by patients.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Skin Research Center-Shahid Beheshti University of Medical Sciences

Street address

The SBMU SRC (Skin Research Center), Shohada-E-Tajrish Educational Hospital, Qods Sq. , Tehran, Iran

City

Tehran

Province

Tehran

Postal code

19899 34148

Approval date

2021-08-07, 1400/05/16

Ethics committee reference number

IR.SBMU.SRC.REC.1400.001

Health conditions studied

1

Description of health condition studied

Macular Amyloidosis

ICD-10 code

e85.8

ICD-10 code description

Other amyloidosis

Primary outcomes

1

Description

clinical improvement of pigmentation

Timepoint

first session and two weeks after final session

Method of measurement

comparison of photos by 2 dermatologist and fotofinder device

2

Description

pigmentation pattern

Timepoint

first session and two weeks after final session

Method of measurement

checking for rippling

3

Description

patient satisfaction

Timepoint

two weeks after final session

Method of measurement

asking the patient

Secondary outcomes**1****Description**

side effects

Timepoint

Since 2weeks after starting of the treatment, till 2 weeks after the last session

Method of measurement

Asking the patient, examination by dermatologist

Intervention groups**1****Description**

Intervention group: First, all patients who have the criteria to enter the Survey, informed i consent to participate in the study is obtained. Prior to treatment, any contamination is removed from the skin with saline solution, and an anesthetic gel (lidocaine 2.5% and prilocaine 2.5%) is used and left on the skin for 30 minutes. The anesthetic gel is then removed from the skin and the site is disinfected with alcohol. One half of the lesion was randomly (using a random number table) treated with microneedling (With 36 needles cartridge and a depth of 0.5 to 1 mm until blood dew was observed) and 5 cc of tranexamic acid solution (500mg / 5cc). The other half is treated with microneedling (With 36 needles cartridge and with a depth of 0.5 to 1 mm until blood clot is observed) and the patient stops using mometasone for 24 hours after each treatment session and The patient avoids washing the areas and after 24 hours,. Patients apply a thin layer of mometasone to the lesions once daily. It is recommended not to use other topical medications during treatment. Four sessions of treatment at two-week intervals are performed on each patient. Patients are examined and photographed with Fotofinder in the first session (baseline time) and two weeks after the end of treatment. Side effects are measured in the second session of treatment and patients are advised in case of any complications at any time to refer to make decisions or the interventions.

Category

Treatment - Drugs

2**Description**

Control group: Other side of the patient's body which is not treated with tranexamic acid. Other interventions are the same as case group

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shohadaye Tajrish Hospital

Full name of responsible person

Mehdi Gheisari

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Shohadaye Tajrish Hospital. 1989934148.Shahrdari St, Tehran Province, Tehran

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2**Recruitment center****Name of recruitment center**

Loghman Hakim Hospital

Full name of responsible person

Mehdi Gheisari

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Skin Research Center Of Shahid Beheshti University Of Medical Sciences

Full name of responsible person

Hamideh Moravvej Farshi

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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

Skin Research Center Of Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mehdi Gheisari

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

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Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

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Person responsible for updating data

Contact

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Full name of responsible person

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Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

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

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All information except the patient name
When the data will become available and for how long
One year after publishing the article
To whom data/document is available
Researchers
Under which criteria data/document could be used

All information except the patient name is available.
From where data/document is obtainable
The researcher of this study, Dr Mehdi Gheisari
What processes are involved for a request to access data/document
sending Email to the researcher: mgheisari@sbmu.ac.ir
Comments