

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

15 Jun 2026

### بررسی اثر بخشی میکرونیدلینگ با ترانگزامیک اسید در مقایسه با میکرونیدلینگ و ویتامین سی در درمان تیرگی دور چشم

#### Protocol summary

##### Study aim

Determination of the effectiveness of microneedling with tranexamic acid in comparison with microneedling with vitamin C in the treatment of dark circles around the eyes

##### Design

A clinical trial with a control group, with parallel, single-blind, randomized, phase 3 groups on 37 patients. The coin toss method will be used for randomization.

##### Settings and conduct

This study is a randomized comparative clinical trial comparing the two sides under the eye. Microneedling will be performed with the aim of achieving spot bleeding in the skin of under eyes. After finishing tranexamic acid on one side, vitamin C is used on the other side. This procedure is performed three times in two weeks (weeks 0, 2 and 4). At each session and before the start of treatment, a photo of the patient is taken. And the pigmentation of the under the eyes is compared at the beginning of treatment, 2,4,6,12 weeks. The results of this study are evaluated by comparing the photographs.

##### Participants/Inclusion and exclusion criteria

People 18 to 50 years old with dark circles around the eyes  
Exclusion criteria: Pregnant women and breastfeeding mothers  
Taking oral contraceptive pills during the last 12 months and during the study  
Existence of any history of coagulation disorders and thrombotic problems  
Consumption of anticoagulants  
Existence of allergy to the studied drugs and topical lidocaine  
History of treatment of dark circles around the eyes during the last six months  
Inherited or acquired diseases of connective tissue  
History of colloidal scarring  
History of using isotretinoin during one year before treatment

##### Intervention groups

Microneedling with tranexamic acid for one side around the eye  
As well as microneedling with vitamin C for the other side of the eye for people with dark circles

##### Main outcome variables

dark circles under the eyes

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200302046669N1**

Registration date: **2021-06-12, 1400/03/22**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-06-12, 1400/03/22**

Update count: **0**

##### Registration date

2021-06-12, 1400/03/22

##### Registrant information

##### Name

Fatemeh Badakhsh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 3337 4866

##### Email address

badakhsh\_f@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-06-10, 1400/03/20

##### Expected recruitment end date

2021-10-22, 1400/07/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

بررسی اثر بخشی میکرونیدلینگ با ترانگزامیک اسید در مقایسه با میکرونیدلینگ و ویتامین سی در درمان تیرگی دور چشم

## Public title

بررسی اثر بخشی میکرونیدلینگ با ترانگزامیک اسید در مقایسه با میکرونیدلینگ و ویتامین سی در درمان تیرگی دور چشم

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

People 18 to 50 years old with dark circles around the eyes

### Exclusion criteria:

Pregnant women and breastfeeding mothers Taking oral contraceptive pills during the last 12 months and during the study Existence of any history of coagulation disorders and thrombotic problemsCommunity Verified icon Taking anticoagulants Existence of allergy to the studied drugs and topical lidocaine History of dark circles treatment around the eyes during the last six months Hereditary or acquired connective tissue diseases History of colloidal scarring History of isotretinoin use within one year before treatment

## Age

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

## Gender

Both

## Phase

3

## Groups that have been masked

- Participant

## Sample size

Target sample size: **37**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Our two comparison groups are both under the eyes, and we have two treatment groups, A and B. For randomization, in treatment method A, microneedling and tranexamic treatment is considered for the right side of the patient's face and microneedling and ascorbic acid treatment is considered for the left side. In treatment method B, it will be the opposite. This means that we will dedicate the right side of the patient's face to the treatment of ascorbic acid microneedling and the left side to the microneedling and tranexamic treatment. Using the coin toss method, method A will be assigned to the patient if observed, and treatment method B will be assigned to the patient if the line is observed.

## Blinding (investigator's opinion)

Single blinded

## Blinding description

The study is one-sided blind in which only the participant is kept blind. The participant is aware of the type of drugs used but is not aware of how they are allocated to the left or right Under the eyes.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Ahvaz Jundishapur University of Medical Sciences

##### Street address

13th floor, Block A ,Treatment and Medical Education ,Headquarters of the Ministry of Health, Iran TV St ,between South Flamek and Zarafshan ,Ghods Town (West), Tehran

##### City

ahvaz

##### Province

Khuzestan

##### Postal code

1111111111

#### Approval date

2021-06-09, 1400/03/19

#### Ethics committee reference number

IR.AJUMS.HGOLESTAN.REC.1400.045

## Health conditions studied

### 1

#### Description of health condition studied

infraorbital dark circle

#### ICD-10 code

H02.71

#### ICD-10 code description

Chloasma of eyelid and periorcular area

## Primary outcomes

### 1

#### Description

Percentage of improvement of opacity after 3 sessions of treatment

#### Timepoint

It is done at the beginning of the study and weeks 2, 4, 8 and 12

#### Method of measurement

عکس برداری با دوربین

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Microneedling to a depth of 2 to 3

mm of the skin with tranexamic acid 3 times at intervals of 2 weeks on one side under the eye. Random selection

**Category**

Treatment - Other

**2****Description**

Intervention group: Microneedling to a depth of 2 to 3 mm with vitamin C skin 3 times 2 weeks apart on one side under the eye. Random selection

**Category**

Treatment - Other

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

Ahvaz Imam Khomeini Hospital

**Full name of responsible person**

Fatemeh Badakhsh

**Street address**

Dermatology clinic, Emam Khomeini Hospital, Azadegan (24 metri) Ave

**City**

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**Province**

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**Postal code**

6155945813

**Phone**

+98 61 3336 6086

**Email**

badakhsh\_f@yahoo.com

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

Ahvaz University of Medical Sciences

**Full name of responsible person**

Mehdi Ahmadi moghadam

**Street address**

Golestan , Ahvaz Jondishapur University of Medical Scinces

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

6135715794

**Phone**

+98 61 3373 8383

**Email**

ahmadi-m@ajums.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor****organization/entity?**

No

**Title of funding source**

Vice Chancellor for Research, Ahvaz 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**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Fatemeh Badakhsh

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dermatology

**Street address**

No. 5, 19th Street, Kianpars

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6155887137

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Fatemeh Badakhsh

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Resident

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

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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

Not applicable

### Title and more details about the data/document

Personal information of participants including age, sex, complications and degree of hyperpigmentation under the eyes before and after microneedling along with tranexamic acid and microneedling with vitamin C

### When the data will become available and for how long

Access period starts 6 months after the results are published

### To whom data/document is available

Researchers working in academic and scientific institutions

### Under which criteria data/document could be used

Dermatologists Academic researchers Permitted analyzes: descriptive

### From where data/document is obtainable

badakhsh\_f@yahoo.com tel : 00989127087284

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

The requested information will be provided to the applicant one month after receiving the email.

### Comments