Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 vascorbic 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 vascorbic 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

Khouzestan

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 periocular 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

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6155945813

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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

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Khouzestan

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6135715794

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+98 61 3373 8383

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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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Fatemeh Badakhsh

Position

Resident

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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
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