

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of different concentrations of mesotherapy with tranexamic acid in patients with the complaint of Darkness around the eyes

Protocol summary

Study aim

To compare different concentrations of mesotherapy with tranexamic acid in improving dark circles around the eyes

Design

A total of 23 people eligible to enter the study in a randomized and double-blind phase 3 study referred to Razi Skin Hospital who undergo mesotherapy with trengsamic acid for dark circles around the eyes in three stages.

Settings and conduct

Subcutaneous injection of tranexamic acid after local anesthesia in the place of darkness around the eyes, 0.05 ml per square meter in three stages in Razi Hospital

Participants/Inclusion and exclusion criteria

inclusion criteria: Darkness around the eyes should not be in the field of atopy Do not breastfeed not pregnant There is no underlying disease Do not have a history of merotherapy and PRP around the eyes exclusion criteria: Darkness around the eyes is in the field of atopy Pregnant or breastfeeding have underlying disease Have a history of mesotherapy and PRP around the eyes

Intervention groups

Patients were randomly assigned to groups of 100 and 10 tranexamic acid concentrations for the eyelid of each eye through a double-blind block randomization method. Thus, each person was considered as a block. Double blocks are made so that the combination of AB Treatment A is injected into the right eyelid of the person and treatment B is injected into the left eyelid. To prepare a random list, it is used in such a way that a random number is selected at each step, if the selected number is between 0 and 4, it is AB combination and if it is between 5 and 9 BA composition is considered

Main outcome variables

darkness and hyperpigmentation around the eyes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240926063171N1**

Registration date: **2024-11-21, 1403/09/01**

Registration timing: **registered_while_recruiting**

Last update: **2024-11-21, 1403/09/01**

Update count: **0**

Registration date

2024-11-21, 1403/09/01

Registrant information

Name

Zahra Sadeghi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-10-22, 1403/08/01

Expected recruitment end date

2025-02-03, 1403/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of different concentrations of mesotherapy with tranexamic acid in patients with the complaint of Darkness around the eyes		Placebo	Not used
Public title		Assignment	Parallel
Comparison of different concentrations of mesotherapy with tranexamic acid in patients with the complaint of Darkness around the eyes		Other design features	
Purpose		Secondary Ids	
Treatment		empty	
Inclusion/Exclusion criteria		Ethics committees	
Inclusion criteria:		1	
Not in the context of atopic dermatitis Has not been treated with PRP and mesotherapy in the last 6 months The form has been taken knowingly Darkness around the eyes has been confirmed by a dermatologist		Ethics committee	
Exclusion criteria:		Name of ethics committee	
pregnancy breastfeeding Receiving anticoagulant medication		Ethics committee of Tehran University of Medical Sciences	
Age		Street address	
From 18 years old to 50 years old		Ghods St., Porsina St., Faculty of Medical Sciences	
Gender		City	
Both		Tehran	
Phase		Province	
3		Tehran	
Groups that have been masked		Postal code	
- Participant - Investigator		1936893813	
Sample size		Approval date	
Target sample size: 23		2023-09-12, 1402/06/21	
Randomization (investigator's opinion)		Ethics committee reference number	
Randomized		IR.TUMS.MEDICINE.REC.1402.336	
Randomization description		Health conditions studied	
Patients were randomly assigned to groups of 100 and 10 trengsamic acid concentrations for the eyelid of each eye through a double-blind block randomization method. Thus, each person was considered as a block. Double blocks are made in such a way that the combination of AB Treatment A is injected into the right eyelid of the person and treatment B is injected into the left eyelid. In order to prepare a random list, it is used in such a way that a random number is selected at each step, if the selected number is between 0 and 4, it is AB combination and if it is between 5 and 9 BA composition is considered. Therefore, we will repeat this process many times until eligible patients enter the study according to the output of the Random Allocation software, which is reported as follows. AB code: 0001 means the left and right eyelids of the first person treated with A and the left eye lid of the first person treated. B should be injected. In addition, the BA code is 0002, which means that the right eyelid of the second patient should be injected with treatment B and the left eyelid of the second patient should be injected with treatment A.		1	
Blinding (investigator's opinion)		Description of health condition studied	
Double blinded		Darkness around the eyes	
Blinding description		ICD-10 code	
Participants The doctor who performs the injection procedure Nurses and health personnel Referrals of participants Data security and monitoring committee Those who prepare the draft of the article be blinded.		ICD-10 code description	
		Primary outcomes	
		1	
		Description	
		darkness and hyperpigmentation around the eyes	
		Timepoint	
		before the start of treatment, three weeks after the start of therapy and the third time 8 to 12 weeks after the start of treatment	
		Method of measurement	
		During three rounds, photos are taken using an 8 megapixel digital camera	
		Secondary outcomes	
		empty	
		Intervention groups	

1

Description

Intervention group:in Intervention group one, patients with dark circles around the eyes, the combination of the same AB means that the lower right eyelid A and the lower left eyelid B are injected

Category

Treatment - Drugs

2

Description

Intervention group: In intervention group 2, patients with dark circles around the eyesThe composition of BA concentration means that the lower right eyelid is injected with concentration B, the lower left eyelid with concentration A.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi skin hospital skin clinic

Full name of responsible person

Dr.Nasim mazloomi tootoonchi

Street address

Razi Skin Hospital, Vahdat Islamic St., Tehran

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Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Ali Akbari Sari

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Faculty of Medicine, Porsina St., Qods St., Tehran

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Nasim mazloomi tootoonchi

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available