Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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

Public title
Comparison of different concentrations of mesotherapy with tranexamic acid in patients with the complaint of Darkness around the eyes
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
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
Exclusion criteria:
pregnancy breastfeeding Receiving anticoagulant medication
Age
From **18 years** old to **50 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **23**
Randomization (investigator's opinion)
Randomized
Randomization description
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.
Blinding (investigator's opinion)
Double blinded
Blinding description
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.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran University of Medical Sciences
Street address
Ghods St., Porsina St., Faculty of Medical Sciences
City
Tehran
Province
Tehran
Postal code
1936893813
Approval date
2023-09-12, 1402/06/21
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1402.336

Health conditions studied

1

Description of health condition studied
Darkness around the eyes
ICD-10 code
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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
Dr Ali Akbari Sari
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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