

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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)

##### Phone

+98 11 4452 5823

##### Email address

dr.shimasadeghi2220070867@gmail.com

##### 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

#### Street address

Razi Skin Hospital, Vahdat Islamic St., Tehran

#### City

Tehran

#### Province

Tehran

#### Postal code

۱۱۹۳۶۴۰۰۲

#### Phone

+98 911 412 8327

#### Fax

+98 21 5563 4461

#### Email

Dr.zahrasadeghi174433@gmail.com

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Tehran University of Medical Sciences

#### Full name of responsible person

Dr Ali Akbari Sari

#### Street address

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

#### City

Tehran

#### Province

Tehran

#### Postal code

۴۵۱۳ ۱۴۶۱۸۸

#### Phone

+98 21 8898 9487

#### Fax

+98 21 8895 3003

#### Email

tumspr@tums.ac.ir

#### 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

#### Street address

Razi Skin Hospital, Vahdat Islamic St., Tehran

#### City

Tehran

#### Province

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#### Postal code

1193640002

#### Phone

+98 21 5563 4461

#### Email

ansarims@sina.tums.ac.ir

#### Web page address

## Person responsible for scientific 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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**Person responsible for updating data****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

**Street address**

Razi Skin Hospital, Vahdat Islamic St., Tehran

**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