

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jun 2026

### Efficacy of platelet-rich plasma injection in combination with tranexamic acid compared with tranexamic acid injection alone in the treatment of macular amyloidosis

#### Protocol summary

##### Study aim

Comparison of the efficacy of platelet-rich plasma injection in combination with tranexamic acid and tranexamic acid injection alone in the treatment of macular amyloidosis.

##### Design

Clinical trial with control group, double-blind, randomized, on 10 patients. The rand function of Excel software was used for randomization.

##### Settings and conduct

Interventions will be performed in the skin and stem cells center.

##### Participants/Inclusion and exclusion criteria

Patients over 18 years of age with a clinical diagnosis of macular amyloidosis who have informed consent to enter the study and have the possibility to attend visits and follow-up sessions.

##### Intervention groups

At the beginning of the study, the affected area in each patient is divided into two parts and the areas are named as A and B. In both mentioned areas, tranexamic acid ampoules are injected intradermally. Next, two envelopes are presented to each of the patients, which contain the letters A and B, and the patient is not aware of the contents of the envelope. By choosing the envelope containing the letter A, platelet-rich plasma is injected at a distance of 1 cm from each other in area A. In area B, normal saline injection is performed as a control group. Also, if you choose the envelope containing the letter B, platelet-rich plasma injection will be done in area B and normal saline injection in area A.

##### Main outcome variables

Improvement of severity of macular amyloidosis lesions

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220808055641N4**

Registration date: **2024-02-03, 1402/11/14**

Registration timing: **prospective**

Last update: **2024-02-03, 1402/11/14**

Update count: **0**

##### Registration date

2024-02-03, 1402/11/14

##### Registrant information

##### Name

Alireza Jafarzadeh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 919 890 7445

##### Email address

alirezajafarzadeh8@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-02-09, 1402/11/20

##### Expected recruitment end date

2024-06-09, 1403/03/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Efficacy of platelet-rich plasma injection in combination

with tranexamic acid compared with tranexamic acid injection alone in the treatment of macular amyloidosis

#### Public title

Efficacy of platelet-rich plasma injection in combination with tranexamic acid compared with tranexamic acid injection alone in the treatment of macular amyloidosis

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Clinical diagnosis of macular amyloidosis Age above 18 years old

##### Exclusion criteria:

Pregnancy Breastfeeding Coagulation disorders

#### Age

From **18 years** old to **65 years** old

#### Gender

Both

#### Phase

1-2

#### Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

#### Sample size

Target sample size: **10**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

At the beginning of the study, the affected area in each patient is divided into two parts and the areas are named as A and B. In both mentioned areas, tranexamic acid ampoules are injected intradermally. Next, two envelopes are presented to each of the patients, which contain the letters A and B, and the patient is not aware of the contents of the envelope. By choosing the envelope containing the letter A, platelet-rich plasma is injected at a distance of 1 cm from each other in area A. In area B, normal saline injection is performed as a control group. Also, if you choose the envelope containing the letter B, platelet-rich plasma injection will be done in area B and normal saline injection in area A. All patients are re-injected with tranexamic acid in the mentioned areas in the 4th and 8th weeks, and in the 4th week, in addition to tranexamic acid, platelet-rich plasma and normal saline are injected in the two previously injected areas. Finally, the evaluation of lesions in the 12th week of The study will begin.

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

At the beginning of the study, the affected area in each patient is divided into two parts and the areas are named as A and B. In both mentioned areas, tranexamic acid ampoules are injected intradermally. Next, two envelopes are presented to each of the patients, which contain the letters A and B, and the patient is not aware of the contents of the envelope.

#### Placebo

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- faculty of medicine

##### Street address

No 6, Avesta Ave, Azadi Blvd, Tehran

##### City

Tehran

##### Province

Mazandaran

##### Postal code

1345643546

#### Approval date

2024-01-03, 1402/10/13

#### Ethics committee reference number

IR.TUMS.MEDICINE.REC.1402.546

## Health conditions studied

### 1

#### Description of health condition studied

Macular amyloidosis

#### ICD-10 code

E85.8

#### ICD-10 code description

Other amyloidosis

## Primary outcomes

### 1

#### Description

improvement of macular amyloidosis

#### Timepoint

The beginning of the study and 1 month after the start of the study and 3 months after the start of the study

#### Method of measurement

sonography;visioface;biometry;cutometry,physician global assessment score;patient global assessment score

## Secondary outcomes

empty

## Intervention groups

## 1

### Description

Intervention group: injection of tranexamic acid in combination with platelet rich plasma and evaluation in 4 weeks, 8 weeks and 12 weeks

### Category

Treatment - Drugs

## 2

### Description

Control group: injection of tranexamic acid in combination with normal saline and evaluation in 4 weeks, 8 weeks and 12 weeks

### Category

Treatment - Drugs

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Hazrat Rasool Akram training and treatment center

#### Full name of responsible person

Alireza Jafarzadeh

#### Street address

Rasoul akram, mazyar mansouri Ave, sattarkhan Blvd, Tehran Town

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#### Province

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#### Postal code

1346544457

#### Phone

+98 919 890 7445

#### Email

alirezajafarzadeh8@gmail.com

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Tehran University of Medical Sciences

#### Full name of responsible person

Mohammadali Nilforoushzadeh

#### Street address

No. 4, Maryam Alley, Kamraniyeh St., Tehran

#### City

Tehran

#### Province

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#### Postal code

1234356765

#### Phone

+98 21 2665 7541

#### Email

alirezajafarzadeh8@gmail.com

### 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

Iran University of Medical Sciences

#### Full name of responsible person

Alireza Jafarzadeh

#### Position

Resident

#### Latest degree

Medical doctor

#### Other areas of specialty/work

Dermatology

#### Street address

No.6, ahmadzadeh ardabili Ave, Avesta Blvd, Azadi Blvd, Tehran Town

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#### Email

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Iran University of Medical Sciences

#### Full name of responsible person

Alireza Jafarzadeh

#### Position

resident

#### Latest degree

Medical doctor

#### Other areas of specialty/work

Dermatology

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Alireza Jafarzadeh

**Position**

resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dermatology

**Street address**

No.6, ahmadzadeh ardabili Ave, Avesta Blvd, Azadi Blvd, Tehran Town

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**Postal code**

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**Phone**

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**Email**

alirezajafarzadeh8@gmail.com

**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**

Yes - There is a plan to make this available

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

En After the completion of the study, all patient data will be shared through the article after de-identification.

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

Access to data starts immediately after the publication of the article.

**To whom data/document is available**

There are no restrictions on people's access to data.

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

There is no restriction on the type of data usage.

**From where data/document is obtainable**

rasool-E-akram hospital, niyayesh Ave, satar khan Blvd, Tehran

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

After receiving the email from the applicant, the data will be sent within a maximum of 6 months.

**Comments**