

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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)

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+98 919 890 7445

Email address

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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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammadali Nilforoushzadeh

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No. 4, Maryam Alley, Kamraniyeh 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

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 scientific inquiries

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Latest degree

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Other areas of specialty/work

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Other areas of specialty/work

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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

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