

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

Comparison of the Effect of Systemic Prednisolone and Topical Tranexamic Acid on Prevention of Rebleeding in Patients with Traumatic Hyphema

Protocol summary

Study aim

Comparison of Effect of Topical Transamic Acid and Systemic Prednisolone in Preventing Rebleeding in Patients with Traumatic Hyphaemia

Design

Intention to treat one-way blind clinical trial with parallel groups, phase 2, dividing 101 patients into two groups at random and giving Prednisolone 1 mg / kg daily in two divided doses to one group and Transamic Acid 5% was given to another group every 6 hours until clot absorbed or up to 5 days (whichever occurred earlier) to randomize sequencing using PASS software. Allocation concealment was also done through envelopes

Settings and conduct

This study includes treatment of Patients with Traumatic Hyphema by systemic Prednisolone and topical Tranexamic acid. 101 patients with traumatic hyphema who were admitted in the "Khatam AlAnbia Hospital" in Mashhad. 44 persons with tranexamic acid treatment and 57 persons with prednisolone treatment.

Participants/Inclusion and exclusion criteria

Acceptance criteria: Patients with Traumatic Hyphema referred to Mashhad Eye "Khatam AlAnbia Hospital"
Exclusion criteria: Microscopic hyphema, Patients with systemic diseases such as diabetes mellitus, hypertension and coagulopathies who taking anticoagulants drugs, patients who have a history of ophthalmic surgery, children under 7 years old, and pregnant women.

Intervention groups

Topical administration of Transamic Acid 5% every 6 hours and systemic prednisolone 1 mg / kg in two divided doses for 5 days or until clot absorption (whichever occurs earlier) in each group

Main outcome variables

Rebleeding in patients with traumatic hyphema

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201110049345N1**

Registration date: **2020-12-01, 1399/09/11**

Registration timing: **retrospective**

Last update: **2020-12-01, 1399/09/11**

Update count: **0**

Registration date

2020-12-01, 1399/09/11

Registrant information

Name

Javad Firoozi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3879 0810

Email address

firoozij951@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-23, 1397/06/01

Expected recruitment end date

2020-03-19, 1398/12/29

Actual recruitment start date

2018-08-23, 1397/06/01

Actual recruitment end date

2020-02-20, 1398/12/01

Trial completion date

2020-03-19, 1398/12/29

Scientific title

Comparison of the Effect of Systemic Prednisolone and Topical Tranexamic Acid on Prevention of Rebleeding in Patients with Traumatic Hyphema

Public title

Effect of Systemic Prednisolone and Topical Tranexamic Acid on Prevention of Rebleeding in Traumatic Hyphema

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with Traumatic Hyphema referred to Mashhad Eye "Khatam AlAnbia Hospital"

Exclusion criteria:

Microscopic hyphema Globe rupture Patients with systemic diseases such as diabetes mellitus, hypertension Posterior segment pathology except commotio retina coagulopathy and taking anticoagulants drugs history of ophthalmic surgery children under 7years old pregnant women.

Age

From 7 years old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: 80

Actual sample size reached: 101

Randomization (investigator's opinion)

Randomized

Randomization description

In order to randomize, sequence production was performed using PASS software. Allocation concealment was also done through envelopes.

Blinding (investigator's opinion)

Single blinded

Blinding description

Participants randomly divided in two groups by random table numbers and take medications.outcome assessors and data analysers don't informed about goal of study.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad university of medical science.

Street address

Knowledge and Health City of Mashhad university of medical science - In the end of Shahid Fakouri Blvd (In front of Fakouri 94) - Mashhad - Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

9177899191

Approval date

2018-08-18, 1397/05/27

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1398.519

Health conditions studied

1

Description of health condition studied

Hyphema

ICD-10 code

H21.0

ICD-10 code description

Hyphema

Primary outcomes

1

Description

Rebleeding

Timepoint

Daily for 5 days and two weeks later.

Method of measurement

Slit lamp biomicroscopy

Secondary outcomes

empty

Intervention groups

1

Description

Patients with traumatic hyphema recived Topical Tranzamic Acid5% made by sterilization specialists of Mashhad University of Medical Sciences were administered every 6 hours for 5 days or until clot absorption (each occurred earlier).

Category

Prevention

2

Description

Patients with traumatic hyphema who were given prednisolone tablets at a dose of 1 mg / kg for 5 days or

until clot absorption (whichever occurs earlier).

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Khatam Al Anbia hospital

Full name of responsible person

Javad Firoozi

Street address

Gharani Blv, Mashhad town

City

Mashhad

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Razavi Khorasan

Postal code

9774117737

Phone

+98 51 3728 1400

Email

Firoozij951@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Khalil Abnous

Street address

Ghoreyshi building, Daneshgah Ave.

City

Mashhad

Province

Razavi Khorasan

Postal code

9195965919

Phone

+98 51 3845 2474

Email

ramresearch@mums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Akbar Derakhshan

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Ophthalmology

Street address

Khatam Al-Anbia Eye Hospital, Aboutaleb Intersection

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

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Person responsible for updating data

Contact

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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

All data of hyphema and rebleeding

When the data will become available and for how long

starting 6 months after publication

To whom data/document is available

All people

Under which criteria data/document could be used

All academic peoples

From where data/document is obtainable

E-mail: firoozij951 @mums.ac.ir

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

As soon as possible

Comments