Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Jun 2026

Survey of Tranexamic acid affect on reduction of secondary hemorrhage in the traumatic hyphema

Protocol summary

Summary

Background & Objectives: Hyphema is defined as blood accumulation in the anterior chamber, of its common causes is the blunt trauma. Hyphema is associated with several complication that secondary hemorrhage is of most important complications. This study undertaken to determine effect of Tranexamic Acid on preventing the recurrent hemorrhage in traumatic hyphema. Methods: This study was a Randomized Controlled Trial one that is accomplished on the 54 patients suffered by traumatic hyphema that were referred to ophthalmology clinic of Alavi Hospital. Twenty eight patient received TEA plus routine treatment and twenty six patients received routine treatment alone. Patients without exclusion criteria including history of eye surgery, Glaucoma, Leukemia, Diabetes Mellitus, Coagulopathy, Rheumatoid Arthritis, Optic nerve atrophy, Uveit, antifibrinolytic and topical steroid intake history entered the study. Visual acuity, rebleed rate, intraocular pressure, hyphema grading and Secondary hemorrhage were measured. Descriptive analysis was performed to summarize patients' demographic characteristics and disease conditions. Students T test and q square and nonparametric tests were carried out to compare the distribution difference between treatment and control groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201106016675N1**
Registration date: **2011-07-19, 1390/04/28**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-07-19, 1390/04/28

Registrant information

Name
Rahim Masoumi
Name of organization / entity
Ardabil University of Medical Science
Country
Iran (Islamic Republic of)
Phone
+98 45 1551 0052
Email address
r.maasoumi@arums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Faculty of medicine, Ardebil university of medical sciences

Expected recruitment start date

2006-03-21, 1385/01/01

Expected recruitment end date

2009-03-21, 1388/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Survey of Tranexamic acid affect on reduction of secondary hemorrhage in the traumatic hyphema

Public title

Survey of Tranexamic acid affect on reduction of secondary hemorrhage in the traumatic hyphema

Purpose

Treatment

Inclusion/Exclusion criteria

Exclusion criteria including history of eye surgery,

Glaucoma , Leukemia , Diabetes Mellitus , Coagulopathy, Rheumatoid Arthritis, Optic nerve atrophy ,Uveit, antifibrinolytic and topical steroid intake history

Age
No age limit

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **54**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

1

Registry name
ندارد

Secondary trial Id
ندارد

Registration date
empty

Ethics committees

1

Ethics committee

Name of ethics committee
Vice chancellor for research, Ardebil University of Medical Sciences

Street address
vice chancellor for research, Ardebil University of medical sciences, Ardebil, Iran

City
Ardebil

Postal code

Approval date
2008-09-02, 1387/06/12

Ethics committee reference number
0301

Health conditions studied

1

Description of health condition studied
Blunt eye trauma

ICD-10 code
H21

ICD-10 code description
Traumatic hyphema

Primary outcomes

1

Description
Rebleeding

Timepoint
3-5 day after bleeding the rebleeding and increase of bleeding were cheked in two group

Method of measurement
Slit lamp examination and record in chek list

Secondary outcomes

1

Description
Visual aquity

Timepoint
3-5 day after bleeding visual aquity were cheked in two group

Method of measurement
Snellen chart , Count finger, Light perception

Intervention groups

1

Description
Twenty eight patients in intervention group received 25 mg/kg per day oral tranexamic acid (TA) into 3 doses for 5 days and received routine treatment including: betamethasone, hematropine, timolol, acetazolamide and chloramphenicol.

Category
Treatment - Drugs

2

Description
Twenty six patients in control group received routine treatment including: betamethasone, hematropine, timolol, acetazolamide and chloramphenicol without tranexamic acid (TA).

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Alavi hospital

Full name of responsible person
dr.Rahim Masoumi

Street address
Alavi hospital,ardebil
City
Ardebil

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Ardebil University of Medical Science
Full name of responsible person
Dr Hadi Piri
Street address
Vice chancellor for research, Ardebil university of medical sciences, Daneshgah st,Ardebil
City
Ardebil
Grant name
بودجه پژوهشی دانشگاه
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Ardebil University of Medical Science
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Ardebil University Medical Science
Full name of responsible person
Dr Rahim Maasumi
Position
Assistant prof in ophtalmology
Other areas of specialty/work
Street address
Eye department, Alavi hospital, Ardebil, Iran
City
Ardebil
Postal code
Phone
+98 45 1551 0052
Fax
Email
r.maasoumi@arums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Ardebil University Medical Sciences
Full name of responsible person
Dr Rahim Masoumi
Position
Assistant prof in Ophtalmology
Other areas of specialty/work
Street address
Eye department, Alavi hospital, Ardebil
City
Ardebil
Postal code
Phone
+98 45 1551 0052
Fax
Email
r.maasoumi@arums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Vice chancellor for research faculty of medicine, Ardebil university medical sciences
Full name of responsible person
Naftchi Parvaneh
Position
Responsible for research unit
Other areas of specialty/work
Street address
Faculty of medicine, Ardebil university of medical sciences, Daneshgah st,Ardebil
City
Ardebil
Postal code
Phone
+98 45 1551 2006
Fax
Email
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty