Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of Tranexamic Acid on conservative treatment of Epidural Hematoma in traumatic patients

Protocol summary

Summary

In this study the effect of Tranexamic Acid on conservative treatment of Epidural Hematoma in traumatic patients will be discussed. This study rondomized- single blind- without the use of a placebo and a single central will be done. In two parallel groups of 50 cases and 50 control men and women aged 18 to 75 years with diagnosis of Epidural Hematoma (with no associated sever traumatic injuries) in Emam Reza Hospital in Tabriz had been hospitalized and do not require to surgical intervention, is selected. The intervention group receive 1 g ampul Tranexamic Acid as loading dose and then 1 g every 8 hours for two days, but control group receive standard treatment of Epidural Hematoma without the use of Tranexamic Acid or placebo. After two days, Spiral Brain CT Scan is performed for all patients and the two groups for some parameters such as the rate of change in Epidural Hematoma diameter, level of consciousness and the rate of need for surgery before and after intervention will be compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014040915657N1**
Registration date: **2014-04-09, 1393/01/20**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2014-04-09, 1393/01/20

Registrant information

Name

Azad Mohamadzade

Name of organization / entity

Rezident of Neurosurgery

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2014-04-21, 1393/02/01

Expected recruitment end date

2016-03-15, 1394/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Tranexamic Acid on conservative treatment of Epidural Hematoma in traumatic patients

Public title

Effect of Tranexamic Acid on treatment of Epidural Hematoma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Head trauma; GCS=15; Epidural hematoma with maximum diameter of 1 cm; Age 18-75 years old; Informed consent to participate in research
Exclusion criteria: GCS less than or equal to 13; Require surgery to evacuate the hematoma; History of anticoagulation therapy; History of head trauma; Occipital hematoma; Multiple trauma; Mid line shift;

History of internal disease; age under 18 and older than 75 years old; During lactation and pregnancy

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences, Daneshgah Avenue, Tabriz, East Azarbayejan, Iran

City

Tabriz

Postal code

5155895164

Approval date

2013-10-12, 1392/07/20

Ethics committee reference number

92105

Health conditions studied

1

Description of health condition studied

Epidural Hematoma

ICD-10 code

S06.4

ICD-10 code description

Epidural haemorrhage

Primary outcomes

1

Description

Maintain or reduce of Epidural Hematoma diameter after intervention

Timepoint

Before intervention and 48 hours after intervention

Method of measurement

Brain CT Scan and measurment of the maximum diameter of the Epidural Hematoma with Millimetrs

2

Description

The rate of change of level of consciousness

Timepoint

At admission and 48 hours after intervention

Method of measurement

Glasgow Coma Score (GCS)

3

Description

The approximate volume of epidural hematoma

Timepoint

At admission and 48 hours after intervention

Method of measurement

Brain CT Scan and measurment of the maximum volume of the Epidural Hematoma with Milliliters

Secondary outcomes

empty

Intervention groups

1

Description

Ampul Tranexamic Acid,1 g as loading dose and then 1 g every 8 Hours in intervention group for two days

Category

Treatment - Drugs

2

Description

In the control group at two days after the trauma, Tranexamic Acid or placebo was not used.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor
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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
Tabriz University of Medical Sciences
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

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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*