Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

The effect of Tranexamic Acid on prevention of increased hemorrhage in Traumatic Brain Injury

Protocol summary

Summary

Objective:The effect of Tranexamic Acid on prevention of increased hemorrhage in Traumatic Brain Injury Design: This randomized double-blind clinical trial will be done on 150 patients with traumatic brain injury. Setting and Conduct: In this study, patients who referred to the hospital within 8 hours of injury; after doing a CT scan of the brain and the existence of a cerebral hemorrhage, will randomly divided into two experimental and control groups. Participants including major eligibility criteria: Inclusion criteria: Any traumatic brain lesion in CT scan such as sub arachnid hemorrhage, intra Cranial hemorrhage, subdural hemorrhage ...; age 15 years and more; non penetrating trauma; the first CT scan within 8 hours after trauma; no need to brain surgery during 8 hours. Exclusion criteria: patients with coagolopathy; serum creatinine more than 2 mg; massive organs injury; hospital admission after 8 hours from trauma; pregnant patients; drugs which induced coaglopathy; patients who are unable to perform secondary CT scan. Intervention: In the experimental group, the initial dose of 1 gr Tranexamic Acid in 100 ml of serum will be infused over 10 minutes and then the maintenance dose of 1 gr in 1000 ml of saline will be infused over 8 hours . In the control group, sodium chloride 0.09% will be used in a similar method. 24 h after drugs administration, patients will evaluate by CT scan. Main outcome measures: Patients will evaluate regarding hemorrhagic mass size, new hemorrhage in CT scan, mass effects on brain tissue, and brain ischemic lesion. Then patient outcome regarding response to treatment, Hemorrhagic mass size increase of at least 25% of its original size, need to brain surgery and patient death or recovery will be assessed. Also the adverse effect of Tranexamic Acid including nausea and vomiting, abdominal pain, diarrhea and vein thrombosis will be recorded. Three months after drug administration, outcome measure will be recorded based on the Glasgow Outcome Scale

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201011202854N6**
Registration date: **2013-02-05, 1391/11/17**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2013-02-05, 1391/11/17

Registrant information

Name
Masoumeh Abedzadeh Kalahroudi
Name of organization / entity
Kashan University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kashan University of Medical Science

Expected recruitment start date

2013-04-04, 1392/01/15

Expected recruitment end date

2014-07-06, 1393/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effect of Tranexamic Acid on prevention of increased hemorrhage in Traumatic Brain Injury

Public title
The effect of Tranexamic Acid on prevention of increased hemorrhage in Traumatic Brain Injury

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Any traumatic brain lesion in CT scan such as sub arachnid hemorrhage, intra Cranial hemorrhage, subdural hemorrhage ...; age 15 years and more; non penetrating trauma; the first CT scan within 8 hours after trauma; no need to brain surgery during 8 hours. Exclusion criteria: patients with coagolopathy; serum creatinine more than 2 mg; massive organs injury; hospital admission after 8 hours from trauma; pregnant patients; drugs which induced coaglopathy; patients who are unable to perform secondary CT scan.

Age
From **15 years** old to **70 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **150**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethical committee of Kashan University of Medical Sciences

Street address
Ravand Road, Kashan University of Medical Sciences,Vice chancellor for research

City
Kashan

Postal code
8715981151

Approval date
2012-12-22, 1391/10/02

Ethics committee reference number
3506/1/5/29/پ

Health conditions studied

1

Description of health condition studied
Brain trauma

ICD-10 code
S06

ICD-10 code description
Intracranial injury

Primary outcomes

1

Description
Hemorrhagic Mass size

Timepoint
Before and 24 hours after drug administration

Method of measurement
Using CT scan

2

Description
The effect of mass on brain tissue

Timepoint
Before and 24 hours after drug administration

Method of measurement
Using CT scan

3

Description
Adverse effect of tranexamic acid

Timepoint
During drug administration till one week

Method of measurement
Observation and patient examination

Secondary outcomes

1

Description
Patient recovery status

Timepoint
3 months after patient discharge

Method of measurement
Based on GCOS

Intervention groups

1

Description
Administration of Tranexamic acid 1 gr in 100 ml serum

as loading dose and then 1 gr in 1000 ml serum during 8 hours

Category

Treatment - Drugs

2

Description

Administration of Normal Salin same as intervention group

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kashan shahid Beheshti Hospital

Full name of responsible person

Dr Esmail fakharian

Street address

Shahid Beheshti Hospital, Ravand Road

City

kashan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Kashan University of Medical Sciences

Full name of responsible person

Dr. Gholamali Hamidi

Street address

Kashan University of Medical Sciences, Vice chancellor for research, Ravand Road

City

Kashan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Kashan 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

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Masoumeh Abedzadeh Kalahroudi

Position

Faculty member, Assistant Professor

Other areas of specialty/work

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Person responsible for scientific inquiries

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Position

Faculty Member, Assistant Professor

Other areas of specialty/work

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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