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

Protocol 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.
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
None

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

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Kashan

Country
Iran (Islamic Republic of)

Postal code
8715981151

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

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

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
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. Esmaiel Fakharian

Street address
Shahid Beheshti Hospital, Ravand Road

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Kashan University of Medical Sciences

Full name of responsible person
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Kashan University of Medical Sciences, Vice chancellor for research, Ravand Road

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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
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
empty

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