Clinical Trial Protocol
Iranian Registry of Clinical Trials
12 Dec 2023

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 arachnoid 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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Iran (Islamic Republic of)
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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
Double blinded

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/

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

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**Description**
Administration of Normal Salin same as intervention group

**Category**
Treatment - Drugs

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**Recruitment centers**

1

**Recruitment center**

Name of recruitment center
Kashan shahid Beheshti Hospital

Full name of responsible person
Dr Esmail Fahkarian

Street address
Shahid Beheshti Hospital, Ravand Road

City
Kashan

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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
Dr. Gholamali Hamidi

Street address
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

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**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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Full name of responsible person
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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