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.

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
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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 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.

**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**
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

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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
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
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Sponsors / Funding sources

1

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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