Clinical Trial Protocol
Iranian Registry of Clinical Trials
03 Jun 2018

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; 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.

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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

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

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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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 Esmail fakharian
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Shahid Beheshti Hospital, Ravand Road
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Sponsors / Funding sources

1
Sponsor
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Vice chancellor for research, Kashan University of Medical Sciences
Full name of responsible person
Dr. Gholamali Hamidi
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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