Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Jul 2026

Evaluating the effect of Tranexamic acid on brain contusion and intracerebral hemorrhage in patients with traumatic brain injury (TBI)

Protocol summary

Study aim
Evaluating the effect of Tranexamic acid on brain contusion and intracerebral hemorrhage in patients with traumatic brain injury (TBI)

Design
A clinical trial with the control group, with parallel groups, double-blind, randomized, phase 3 on 80 patients

Settings and conduct
This study is a randomized clinical trial that will be performed in Kashan's Shahid Beheshti Hospital. 40 patients in each group, receiving tranexamic acid and control, will be evaluated. In order to blind the study, syringes containing tranexamic acid and normal saline, will be drawn, coded by one of the colleagues and provided to the nurses of the relevant wards to inject into the patients under study, based on random blocking. None of the physicians or nurses were aware of the type of medication used for the patients

Participants/Inclusion and exclusion criteria
Inclusion criteria: All patients over 13 years of age with blunt traumatic brain injury referred to the emergency department who have been less than 3 hours from the time of the accident to the arrival and have cerebral hemorrhage on CT scan. Exclusion criteria: Major organ damage requiring surgical intervention during the first 3 hours, Taking any medication that interferes with homeostasis.

Intervention groups
Intervention group: Tranexamic acid drug, produced by Iran Daroo company, IR Iran, is infused with the initial dose of 1 g per 100 ml of serum within 10 minutes and then with a dose of 1 g per 1000 ml of serum for 8 hours, as maintenance dose. Control group: Placebo, containing normal saline serum produced by Iran Daroo Co, IR Iran, is infused with an initial dose of 1 gr in 100 cc normal saline in 10 minutes and continued with dose of 1 gr in 1000 cc in 8 hours as maintenance dose.

Main outcome variables
Brain contusion and intracerebral hemorrhage

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190422043339N1**
Registration date: **2021-12-03, 1400/09/12**
Registration timing: **retrospective**

Last update: **2021-12-03, 1400/09/12**
Update count: **0**

Registration date
2021-12-03, 1400/09/12

Registrant information

Name
Voorya Nouranipour

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 31 5554 0026

Email address
voorya.nooranipoor.1990@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-09-23, 1397/07/01

Expected recruitment end date
2020-03-19, 1398/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Evaluating the effect of Tranexamic acid on brain contusion and intracerebral hemorrhage in patients with traumatic brain injury (TBI)

Public title
the effect of hemorrhage preventing medication
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All patients over 13 years of age with blunt traumatic brain injury were referred to the emergency department less than 3 hours after the accident. Patients on CT scan have cerebral intraparenchymal hemorrhage upon arrival.
Exclusion criteria:
Major damage to organs requiring surgical intervention within the first 3 hours Get any medication that disrupts homeostasis
Age
From **13 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Random allocation of patients (randomization unit is "person") into two groups of 40 people was performed using a random quadruple block method, that is done through the website: www.sealedenvelope.com. In each of the 20 quadruple blocks, 2 patients will receive medication (tranexamic acid) and 2 patients will receive placebo (normal saline). It should be noted that this study is a three-blind study in which physicians and nurses, patients and analyst will be unaware of patient groups.
Blinding (investigator's opinion)
Double blinded
Blinding description
In order to blind the study, syringes containing tranexamic acid and normal saline were pre-drawn, coded, and delivered to the nurses of the relevant wards to inject into the patients under study based on random blocking. None of the physicians and nurses knew the type of medication used for the patients and only one of the implementers of the project knew the medication's code, so that in case of any problem or complication for the patients, he/she would break the medication's code and inform the relevant physician.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kashan University of Medical Sciences
Street address
School of Medicine, Nurse Blvd., Qotb Ravandi Blvd.
City
Kashan
Province
Isfehan
Postal code
8715981151
Approval date
2019-03-06, 1397/12/15
Ethics committee reference number
IR.KAUMS.MEDNT.REC.1398.004

Health conditions studied

1

Description of health condition studied
intracranial hematoma and contusion
ICD-10 code
S06.3
ICD-10 code description
Focal traumatic brain injury

Primary outcomes

1

Description
Brain contusion
Timepoint
At baseline, 24 and 48 hours after injection
Method of measurement
Brain CT scanning

2

Description
intracerebral hemorrhage
Timepoint
At baseline, 24 and 48 hours after injection
Method of measurement
Brain CT scanning

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Tranexamic acid made in Iran and Iran Daru Pharmaceutical Company is infused with an initial dose of 1 g per 100 ml of serum within 10 minutes and then infused with a 1 g per 1000 ml maintenance dose of serum for 8 hours.
Category
Treatment - Drugs

2

Description
Control group: The placebo group was infused with normal saline made in Iran and Iran Daru Pharmaceutical Company with an initial dose of 1 g per 100 ml of serum within 10 minutes and then infused with a maintenance dose of 1 g per 1000 ml of serum for 8 hours.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshty Hospital
Full name of responsible person
Esmaeel Fakharian
Street address
Shahid Beheshty Hospital-Nurse Blvd-Qotb Ravandi BLVD
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Hamidreza Banafsheh
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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
Kashan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Esmaeel Fakharian
Position
Professor
Latest degree
Specialist
Other areas of specialty/work
Neurosurgery
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Part of the data can be shared.
When the data will become available and for how long
The data will be available, three months after the publication.
To whom data/document is available
Academic researchers, physicians, and medical students, and treatment staff personnel
Under which criteria data/document could be used
Use to improve the treatment process of patients and to plan the same projects
From where data/document is obtainable
Dr.Esmaeel Fakharian Neurosurgery ward, Shahid Beheshti Hospital, Qotbe ravandi BLVD, Kashan Tel: 00983155540026 efakharian@gmail.com
What processes are involved for a request to access data/document
The request will be sent by email, after survey.
Comments