Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluating the effect of tranexamic acid on prevention of brain contusion, a clinical trial

Protocol summary

Study aim
evaluating the effect of tranexamic acid on prevention of the evolution of brain contusion in patients with brain injury
Design
randomization is performed using tables of random numbers. patients are allocated randomly to either case or control groups
Settings and conduct
this study is performed in Shohadaye Hafte Tir Hospital on the traumatic patients.
Participants/Inclusion and exclusion criteria
inclusion criteria: non-surgical patients with moderate to severe head trauma (GCS: 3-12) with brain contusion
exclusion criteria: other active bleeding sites other causes for use of tranexamic acid renal failure and Cr more than 2
Intervention groups
in the case group 1 gr tranexamic acid is administered at presentation and 1 gr after 8 hours. in control group normal saline is administered at the same timing
Main outcome variables
prevention or slowing the evolution of the brain contusion after measurement of its volume in serial CT scan

General information

Reason for update
Acronym
تاک
IRCT registration information
IRCT registration number: **IRCT20181225042112N1**
Registration date: **2019-02-14, 1397/11/25**
Registration timing: **registered_while_recruiting**

Last update: **2019-02-14, 1397/11/25**
Update count: **0**

Registration date
2019-02-14, 1397/11/25

Registrant information
Name
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-12-22, 1397/10/01
Expected recruitment end date
2019-12-22, 1398/10/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluating the effect of tranexamic acid on prevention of brain contusion, a clinical trial

Public title
Tranexamic acid in brain contusion clinical trial
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
non-surgical patients with moderate to severe head trauma (GCS: 3-12) with brain contusion
Exclusion criteria:

active bleeding in other sites other causes that necessitates use of tranexamic acid renal failure and creatinine more than 2

Age

No age limit

Gender

Both

Phase

1-2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

using randomization numbers who are kept by hospital's pharmacy moderator.

Blinding (investigator's opinion)

Triple blinded

Blinding description

randomization tables are produced and is kept by the hospitals pharmacy moderator. drug and placebo in identical forms are delivered to the nurses according to the tables.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Hazrat Rasoul Akram Hospital, Niayesh St., Sattar khan Ave., Tehran

City

Tehran

Province

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Postal code

1445613131

Approval date

2018-10-28, 1397/08/06

Ethics committee reference number

IR.IUMS.REC.1397.534

Health conditions studied

1

Description of health condition studied

traumatic brain injury

ICD-10 code

S06.3

ICD-10 code description

Focal traumatic brain injury

Primary outcomes

1

Description

contusion evolution

Timepoint

every day in a week

Method of measurement

measuring the CT scan cuts

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: administration of tranexamic acid

Category

Treatment - Drugs

2

Description

Control group: administration of normal saline

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohadaye Hafte Tir Hospital

Full name of responsible person

Amin Jahanbakhshi

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Shahid Rajaii Highway

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Iran 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
Iran University of Medical Sciences
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

area and volume of contusion in CT scan

When the data will become available and for how long

unlimited

To whom data/document is available

unlimited

Under which criteria data/document could be used

for research

From where data/document is obtainable

corresponding author

What processes are involved for a request to access data/document

official letter or email from an academic center

Comments