

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 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

تاکی

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

Amin Jahanbakhshi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

jahanbakhshi.a@iums.ac.ir

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

Tehran

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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1998531026

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

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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

Full name of responsible person

Amin Jahanbakhshi

Position

assistant professor

Latest degree

Specialist

Other areas of specialty/work

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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