

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 2026

The effect of Tranexamic acid administration on non-traumatic Intracerebral hemorrhage in contrast with placebo in Namazi hospital.

Protocol summary

Study aim

comparison between Tranexamic acid and Placebo effect on treatment of cerebral intra-paranchymal hemorrhage in Namazi hospital.

Design

A concealed, randomized, single-blinded, sham-controlled clinical trial with a parallel group design of 100 patients, enroll between 2020 and 2021 and follow for 6 months. Randomization in eligible patients will be carried out via permuted block randomization with 10 blocks that include 10 numbers.

Settings and conduct

In this study, patients with intraparenchymal hemorrhage will be participated who admitted in Namazi hospital. In this Single blinded study, patients will be blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age between 18-75 years old, acute intraparenchymal hemorrhage (within last 12 hours) without history of trauma. Exclusion criteria: multiple intraparenchymal hemorrhage, contraindication for antifibrinolytic use, massive intraparenchymal hemorrhage (>70cc), brain stem hemorrhage, aneurysm, vascular malformation, hemorrhagic transformation after stroke, Cerebral venous thrombosis, thrombolytic therapy, brain tumors, infections, cranial surgery within 24 hours, CVA, renal failure (GFR < 50mmol), pregnancy and history of anaphylactic shock after tranexamic use.

Intervention groups

Intervention group received 1g tranexamic acid intravenously in 100 ml normal saline 0.9% within 10 minutes and 1g tranexamic acid in 500 ml normal saline 0.9% within 8 hours. In control groups same amounts of normal saline 0.9% will be injected.

Main outcome variables

Main outcome: In-hospital mortality, hematoma expansion in follow up brain CT scan, prehematoma edema, functional outcome after 90 days with Modified Rankin Scale (MRS)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220520054927N1**

Registration date: **2022-09-08, 1401/06/17**

Registration timing: **registered_while_recruiting**

Last update: **2022-09-08, 1401/06/17**

Update count: **0**

Registration date

2022-09-08, 1401/06/17

Registrant information

Name

Seyed ali Alavi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-23, 1401/05/01

Expected recruitment end date

2023-03-20, 1401/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Tranexamic acid administration on non-traumatic Intracerebral hemorrhage in contrast with placebo in Namazi hospital.

Public title

The effect of Tranexamic acid administration on non-traumatic Intracerebral hemorrhage in contrast with placebo

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age between 18-75 years old Acute non-traumatic intraparenchymal hemorrhage Less than 12 hours since bleeding

Exclusion criteria:

Multiple intra-parenchymal hemorrhage Contraindication for Anti-fibrinolytic treatment Massive intraparenchymal hemorrhage (>70cc) Spontaneous ICH cerebral aneurysm or vascular anomalies Post CVA hemorrhagic formation Cerebral venous thrombosis Anti-thrombotic therapy Brain tumor or infection

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, eligible patients will be randomized as case and control groups. In the case group, they will receive Tranexamic acid and in the control group, they will receive a placebo. To allocate participants in case and control groups, permuted block randomization will be used. Based on the sample size (100 patients), 10 blocks that contain 10 numbers will be created. We use Random allocation software to perform randomization.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, participants in both groups will be blinded to drug or placebo administration via injection of the same amount with the same physical properties of drug or placebo

Placebo

Used

Assignment

Parallel

Other design features**Secondary IDs**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research ethic committees of school of medicine, Shiraz university of medical sciences.

Street address

Zand street, namazi hospital

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Shiraz

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Postal code

7193613565

Approval date

2021-12-27, 1400/10/06

Ethics committee reference number

IR.SUMS.MED.REC.1400.513

Health conditions studied**1****Description of health condition studied**

Intraparenchymal hemorrhage

ICD-10 code

I61.0

ICD-10 code description

Nontraumatic intracerebral hemorrhage in hemisphere, subcortical

Primary outcomes**1****Description**

Expansion of intraparenchymal hemorrhage

Timepoint

Before intervention, 1 and 3 days later

Method of measurement

Brain CT scan

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: After admission in hospital and diagnosis of intraparenchymal hemorrhage with radiologic evaluations, patients will receive Injection of 1gr tranexamic acid intravenously in 100cc normal saline 0.9% within 10 minutes, then 1gr tranexamic acid in 50cc normal saline 0.9% within 8 hours. Also, all patients in intervention group will be treated with necessary routine drugs such as anticonvulsive and antihypertension drugs.

Category

Treatment - Drugs

2**Description**

Control group: Control group: In this group receive the same anticonvulsive and antihypertension drugs, also same amount of normal saline 0.9% but distilled water will be injected instead of tranexamic acid as a placebo

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Namazi hospital

Full name of responsible person

Mohammad Jamali

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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?**

No

Title of funding source

Shiraz Medical University of Science

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**

Shiraz University of Medical Sciences

Full name of responsible person

Mohammad Jamali

Position

Assistant professor

Latest degree

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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

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

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

Data Dictionary

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

Title and more details about the data/document

Full text of original article Data file

When the data will become available and for how long

starting 6 months after publication

To whom data/document is available

available for people working in academic institutions and who works in businesses

Under which criteria data/document could be used

Any analytic tests with authors permission is possible.

From where data/document is obtainable

Via Email or telephone numbers

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

Required data will be sent to Email

Comments