Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 hemorhage 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 mounts. Randomization in eligible patients will be carried out via permuted block randomization with10 blocks that include 10 numbers.

Settings and conduct

In this study, patients with intraparanchymal hemorrhage will be participated who admitte 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 intraparanchimal hemorrhage(within last 12 hours) without history of truama. Exclusion criteria: multiple intraparanchimal hemorrhage, contraindication for antifibrinolytic use, massive intraparanchimal hemorrhage (>70cc), brain stem hemorrhage, anurysem, 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 hstory of anafilactic shock after tranexamic use.

Intervention groups

Intervention group recieved 1gr tranexamic acid intravenously in 100 ml normal salin0.9% within 10 minutes and 1gr tranexamic acid in 500 ml normal salin0.9% within 8 hours. In control groups same amounts of normal salin 0.9% will be injected.

Main outcome variables

Main outcome: In-hospital mortality, hematom expantion in follow uo brain CT scan, prehematomal edema, functional outcome after 90 days wit 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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+98 939 310 8224

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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 intra-paranchimal hemorrhage Less than 12 hours since bleeding

Exclusion criteria:

Multiple intra-paranchimal hemorrhage Contraindication for Anti-phybrinolytic treatment Massive ntra-paranchimal hemorrhage (>70cc) Stem ICH cerebral aneurysm or vascular anomalies Post CVA hemorrhagic formation Cerebral venous thrombosis Anti-thrombolytic 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

City

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Province

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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

Intraparanchymal hemorrhage

ICD-10 code

I61.0

ICD-10 code description

Nontraumatic intracerebral hemorrhage in hemisphere, subcortical

Primary outcomes

1

Description

Expansion of intraparanchymal 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 intra paranchimal hemorrhage with radiologic evaluations, patients will receive Injection of 1gr tranexamic acid intravenously in 100cc normal salin 0.9% within 10 minutes, then 1gr tranexamic acid in 50cc normal salin 0.9% within 8 hours. Also, all patients in intervention group will be treated with necessary routine drugs such as anticonvusive 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 salin 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

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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
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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

Requaired data will be sent to Email

Comments