Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

efficacy of intravenous vitamin C combined with intravenous tranexamic acid in improving outcomes of intracerebral/intraventricular hemorrhages in non-traumatic ICH patients

Protocol summary

Study aim

-Evaluation of the combined therapeutic effect of intravenous tranexamic acid and intravenous Vitamin C in preventing the progression of intracerebral hemorrhage, improving three-month functional impairment (based on changes in the mRS score) and reducing mortality in patients with non-traumatic ICH patients.

Design

The clinical trial is a parallel-group, double-blind, randomized, phase 3 study with a control group, involving 60 patients. Permuted Block Randomization will be used to allocate patients into the two control and intervention groups.

Settings and conduct

Study Design: Double-blind trial at Imam Reza Hospital, Tabriz, monitoring patients for 90 days post-intervention. Blinding: Both participants and the executive study team will be blinded to group assignments (intervention vs. control). Follow-up: Assessments conducted at 24 hours, 3, 7, 30, and 90 days post-admission.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Adults (>18 yrs) with acute, non-traumatic intracerebral hemorrhage, presenting within 6 hours of symptom onset. Exclusion Criteria: Patients with hemorrhage due to anticoagulants, thrombolysis, or underlying structural issues (e.g., AVM, aneurysm, tumor).

Intervention groups

Intervention Group: Receives a loading dose of IV tranexamic acid (1g in 100ml NS), followed by 1g IV infusion over 8 hours (total 2g/24h), plus 4g IV vitamin C daily for 4 days. Control Group: Receives only IV tranexamic acid as part of standard ICH care. Treatment Duration: Tranexamic acid for 24 hours, vitamin C for 4 days in the intervention group.

Main outcome variables

Prevention of intracerebral hemorrhage progression, improvement in three-month functional outcomes (based on changes in the modified Rankin Scale - mRS), and reduction in mortality rate in patients with non-traumatic intracerebral hemorrhage

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170609034406N15**
Registration date: **2026-03-31, 1405/01/11**
Registration timing: **prospective**

Last update: **2026-03-31, 1405/01/11**
Update count: **0**

Registration date

2026-03-31, 1405/01/11

Registrant information

Name

Afshin Gharekhani

Name of organization / entity

Faculty of Pharmacy/Tabriz University of Medical Sciences

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Recruitment status

Not yet recruiting

Funding source

Expected recruitment start date

2026-06-22, 1405/04/01

Expected recruitment end date
2026-09-23, 1405/07/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
efficacy of intravenous vitamin C combined with intravenous tranexamic acid in improving outcomes of intracerebral/intraventricular hemorrhages in non-traumatic ICH patients

Public title
Evaluation of the combined therapeutic effects of intravenous Vitamin C and intravenous tranexamic acid on improving outcomes in patients with non-traumatic ICH
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Individuals over 18 years of age with acute, non-traumatic intracerebral hemorrhage, within a maximum of 6 hours from the onset of bleeding
Exclusion criteria:
Patients with intracerebral hemorrhage secondary to anticoagulant use, thrombolysis, or known structural abnormalities such as arteriovenous malformations (AVMs), aneurysms, or tumors Patients with contraindications to tranexamic acid (such as active intravascular clotting, a history of thromboembolic diseases, or hypersensitivity to tranexamic acid) Modified Rankin Scale (mRS) >4 Glasgow coma scale <5 Intracerebral hemorrhage secondary to trauma Subarachnoid hemorrhage (SAH) Subdural hemorrhage (SDH) Epidural hemorrhage (EDH) Pregnant or lactating women at the time of randomization Geographical or other factors that hinder follow-up at 90 days, such as lack of a permanent address or contact phone number
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **60**
More than 1 sample in each individual
Number of samples in each individual: **30**
A total of 60 patients (30 patients in each group) with acute non-traumatic intracerebral hemorrhage, meeting the predefined inclusion and exclusion criteria, will be enrolled and allocated into the intervention and control groups. Patients in the intervention group will receive 1 g of intravenous tranexamic acid diluted in 100 mL of normal saline as a loading dose, followed by an additional 1 g administered as an intravenous infusion over eight hours (a total of 2 g of intravenous tranexamic acid within 24 hours), along with 4 g of intravenous vitamin C daily for four consecutive days. The control group will receive only intravenous tranexamic acid in addition to all other standard treatments and routine care related to ICH.
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, Permuted Block Randomization is used to allocate patients into two groups: the control and the intervention groups. A total of 25 blocks of 4 participants are planned. In this method, each block contains an equal number of patients in the intervention and control groups. Random numbers in this study are generated using Microsoft Excel to create the random block assignments as well as the random allocation of patients to the groups.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this phase 3 clinical trial, a double-blind design will be implemented to ensure the validity of the results and to minimize any potential sources of bias. This approach guarantees that neither the participants (patients) nor the study personnel (including physicians, nurses, data collectors, and outcome assessors) are aware of the treatment allocation for each patient within the intervention or control groups. According to the study protocol, the control group will receive intravenous tranexamic acid, while the intervention group will receive intravenous tranexamic acid in combination with intravenous vitamin C. To maintain blinding, both injectable agents (tranexamic acid and vitamin C) will be prepared and packaged in a manner that ensures complete similarity in appearance, color, volume, odor, and other physical characteristics. All injectable solutions will be labeled with unique identification codes, and the code-allocation key (indicating which code corresponds to which treatment combination) will be securely kept by an independent individual or entity with no involvement in patient care, trial execution, or data collection and analysis. This strategy ensures that information regarding the administration of active vitamin C remains concealed until the completion of data collection and analysis, thereby preventing any potential influence on clinical judgment or outcome assessment.
Placebo
Not used
Assignment
Parallel
Other design features
Double-blind, Randomized, Block-randomized Clinical Trial. Intervention Group: Intravenous TXA + Intravenous Vitamin C. Control Group: Intravenous TXA, along with other standard treatments and care for ICH. Monitoring: At 24 hours, 3 days, 7 days, 30 days, and 90 days.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Tabriz University of Medical Sciences

Street address
No 2 Central Building , Tabriz University of Medical Sciences , Golgasht Street , Tabriz

City
Tabriz

Province
East Azarbaijan

Postal code
5165665931

Approval date
2026-03-17, 1404/12/26

Ethics committee reference number
IR.TBZMED.REC.1404.891

Health conditions studied

1

Description of health condition studied
Non-traumatic intracerebral and intraventricular hemorrhage

ICD-10 code
I61

ICD-10 code description
Nontraumatic intracerebral hemorrhage

Primary outcomes

1

Description
Functional outcome measured by the Modified Rankin Scale (mRS) score at day ninety after randomization

Timepoint
Baseline before randomization and day ninety (or discharge day) after randomization

Method of measurement
Use of the modified Rankin Scale questionnaire (range 0 to 6) administered in person by a trained assessor who is blinded to group allocation

Secondary outcomes

1

Description
Hematoma expansion defined as an increase in intracerebral hemorrhage volume of at least thirty three percent or at least six milliliters between baseline and follow up imaging.

Timepoint
Baseline imaging at enrollment and follow up imaging at twenty four to seventy two hours after randomization

Method of measurement
Non contrast computed tomography scans with hematoma volume measured by the ABC divided by two method or by planimetry on the hospital imaging workstation read by a radiologist who is blinded to group allocation

2

Description
All-cause mortality up to the day of discharge (or death) following randomization

Timepoint
From the time of randomization until the day of discharge (or death)

Method of measurement
Review of the hospital record and follow-up telephone assessment by the blinded assessor, confirmed by official records where permitted

Intervention groups

1

Description
Intervention group: Patients in the intervention group will receive 1 gram of intravenous tranexamic acid diluted in 100 milliliters of normal saline as a loading dose, followed by an intravenous infusion of 1 gram over eight hours (a total of 2 grams of intravenous tranexamic acid within 24 hours), along with 4 grams of intravenous vitamin C daily for four days.

Category
Treatment - Drugs

2

Description
Control group: They will receive only intravenous tranexamic acid in addition to other standard treatments and care for ICH.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Emam Reza Hospital

Full name of responsible person
Afshin Gharekhani

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Golgasht street

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Sponsors / Funding sources

1

Sponsor

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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

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Afshin Gharekhani

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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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
Undecided - It is not yet known if there will be 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
Deidentified IPD (baseline and follow-up clinical variables, outcomes, adverse events), study protocol, statistical analysis plan, blank informed consent form, analytic code, and data dictionary.
When the data will become available and for how long
Available upon publication of the primary results and for three years thereafter.
To whom data/document is available
Qualified researchers from academic or non-profit institutions with a sound research proposal.
Under which criteria data/document could be used
Non-commercial use for scientifically and ethically appropriate projects; approval by an institutional review board or ethics committee when applicable; execution of a data use agreement that protects participant privacy.
From where data/document is obtainable
Contact the Principal Investigator via email (forouzan.abbasgholizadeh1998@gmail.com). Documents may also be posted on the Tabriz University of Medical Sciences repository if available.
What processes are involved for a request to access data/document
Submit a brief proposal and analysis plan to the Principal Investigator. Requests are reviewed by the study steering team within 30 days. If approved, a data use agreement will be executed and the deidentified dataset, code, and data dictionary will be shared via a secure link.
Comments