Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Evaluating the effect of Tranexamic Acid on the Prognosis of Patients with Intracerebral Hemorrhage

Protocol summary

Study aim
Determining the Effect of Tranexamic Acid on the Prognosis of Patients with Intracerebral Hemorrhage Presenting to Imam Khomeini Hospital, Urmia.

Design
This is a prospective, open-label, randomized clinical trial (RCT) with parallel groups, phase 2, on 50 patients. Patients will be randomly assigned into two equal groups (25 patients each) using a computer-generated random number table.

Settings and conduct
In the intervention group, patients will receive standard treatment (blood pressure control, head elevation, normal saline, blood glucose control, subcutaneous heparin, anticonvulsants, acetaminophen, mannitol) along with tranexamic acid (Raha Pharmaceutical) at a weight-adjusted dose: 15–20 mg/kg IV bolus over 10 minutes, followed by 15 mg/kg IV infusion over 8 hours. The control group will receive only standard treatments without tranexamic acid.

Participants/Inclusion and exclusion criteria
inclusion criteria : Age 18 years and older Confirmation of spontaneous intracerebral hemorrhage on initial CT scan No immediate need for surgical evacuation of the hematoma exclusion criteria: Under 18 years old Bleeding caused by an aneurysm Malignancy or structural lesions of the brain Pregnancy or breastfeeding Known coagulation disorders Renal failure History of thrombosis Any type of bleeding other than ICH

Intervention groups
In the intervention group, patients will receive standard treatment (blood pressure control, head elevation, normal saline, blood glucose control, subcutaneous heparin, anticonvulsants, acetaminophen, mannitol) plus tranexamic acid (Raha Pharmaceutical) at 15–20 mg/kg IV bolus over 10 minutes, then 15 mg/kg IV infusion over 8 hours. The control group will receive only standard treatments without tranexamic acid.

Main outcome variables
Intracerebral hemorrhage volume (ICH volume)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20241016063386N2**
Registration date: **2025-12-27, 1404/10/06**
Registration timing: **prospective**

Last update: **2025-12-27, 1404/10/06**
Update count: **0**

Registration date
2025-12-27, 1404/10/06

Registrant information

Name
Fatemeh Hamzeh

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-02-20, 1404/12/01

Expected recruitment end date
2027-02-20, 1405/12/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Evaluating the effect of Tranexamic Acid on the Prognosis of Patients with Intracerebral Hemorrhage

Public title
Evaluating the effect of Tranexamic Acid on the Prognosis of Patients with Intracerebral Hemorrhage

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age ≥ 18 years Diagnosis of spontaneous intracerebral hemorrhage (ICH) confirmed by initial brain CT scan Admission to the emergency department Hemodynamic stability after initial supportive management Provision of written informed consent by the patient or legal guardian

Exclusion criteria:
Urgent need for surgical intervention for hematoma evacuation Intracerebral hemorrhage secondary to trauma, aneurysm, malignancy, or structural brain lesions Pregnancy or breastfeeding Known coagulation disorders or use of uncontrollable anticoagulant therapy Moderate to severe renal failure History of thrombosis or active thromboembolic disease Hemodynamic instability despite initial therapeutic interventions Inability to obtain informed consent from the patient or legal guardian due to clinical or legal reasons

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, randomization will be performed using block randomization at the individual level. After determining the sample size (50 patients) and two study groups (intervention and control), a random allocation sequence consisting of 25 blocks of size two (block size = 2) will be generated using a computer-based random number generator prior to study initiation. Patients will be enrolled consecutively based on the time of entry into the study, and after confirming eligibility criteria and obtaining informed consent, they will be assigned sequentially according to the pre-generated randomization list. The randomization list will be kept confidential, and the investigator responsible for patient recruitment will be unaware of group allocation prior to assignment.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Other

Other design features
To provide documented clinical evidence to guide decision-making regarding the inclusion of tranexamic acid (TXA) in treatment protocols for patients with spontaneous intracerebral hemorrhage (sICH), in a manner that is compatible with the capacities and limitations of the country's health system and leads to a reduction in mortality and disability due to this disease.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Imam Khomeini Educational and Medical Center - Urmia University of Medical Sciences (Research Ethics

Street address
Imam Khomeini University Hospital., Ershad AVE.,Modarres Blvd., Urmia., IRAN

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Approval date
2025-12-03, 1404/09/12

Ethics committee reference number
IR.UMSU.HIMAM.REC.1404.099

Health conditions studied

1

Description of health condition studied
Nontraumatic intracerebral hemorrhage

ICD-10 code
I61

ICD-10 code description
Nontraumatic intracerebral hemorrhage

Primary outcomes

1

Description
(Intracerebral Hemorrhage Volume)

Timepoint
CT scan and calculation of bleeding volume will be performed at baseline, 48 hours after admission, and on the seventh day after study entry.

Method of measurement
The volume of intracerebral hemorrhage is calculated using a brain CT scan and based on the standard ABC/2 formula.

Secondary outcomes

empty

Intervention groups

1

Description
In the intervention group, in addition to standard treatment, Tranexamic Acid (manufactured by Raha Pharmaceutical Company) will be administered at a dose modified based on the patient's weight:Initial dose: 15–20 mg/kg as an intravenous bolus over 10 minutes.Maintenance dose: 15 mg/kg as an intravenous infusion over 8 hours.Standard treatment in this group includes the following measures:Blood pressure control in the range of 130–150 mmHgKeeping the patient's head elevated at a 30-degree angleAdministration of normal saline to maintain hydration and blood volumeBlood glucose control in the range of 150–180 mg/dLSubcutaneous heparin administration after hemodynamic stabilization to prevent thrombosisCommencement of anticonvulsants in case of seizuresFever control with acetaminophenMannitol usage in case of increased intracranial pressure (ICP)

Category
Treatment - Drugs

2

Description
In the control group, patients will receive standard treatment, which includes the following measures:Blood pressure control in the range of 130–150 mmHgKeeping the patient's head elevated at a 30-degree angleAdministration of normal saline to maintain hydration and blood volumeBlood glucose control in the range of 150–180 mg/dLSubcutaneous heparin administration after hemodynamic stabilization to prevent thrombosisCommencement of anticonvulsants in case of seizuresFever control with acetaminophenUse of mannitol in case of increased intracranial pressure (ICP)

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Khomeini Hospital in Urmia

Full name of responsible person
Dr.Fatemeh Hamzeh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Oroumia University of Medical Sciences

Full name of responsible person
Dr. Saber Gholizadeh

Street address
Resalat Boulevard .,Emergency Alley .,Urmia University of Medical Sciences

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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
Oroumia 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
Oroumia University of Medical Sciences

Full name of responsible person
Dr.Fatemeh Hamzeh

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Neurology

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

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