

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

Country

Iran (Islamic Republic of)

Phone

+98 44 3345 7286

Email address

hamzeh.f@umsu.ac.ir

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 \geq 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

City

Urmia

Province

West Azarbaijan

Postal code

5715789397

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 mmHg. Keeping the patient's head elevated at a 30-degree angle. Administration of normal saline to maintain hydration and blood volume. Blood glucose control in the range of 150-180 mg/dL. Subcutaneous heparin administration after hemodynamic stabilization to prevent thrombosis. Commencement of anticonvulsants in case of seizures. Fever control with acetaminophen. Mannitol 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 mmHg. Keeping the patient's head elevated at a 30-degree angle. Administration of normal saline to maintain hydration and blood volume. Blood glucose control in the range of 150-180 mg/dL. Subcutaneous heparin administration after hemodynamic stabilization to prevent thrombosis. Commencement of anticonvulsants in case of seizures. Fever control with acetaminophen. Use 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

Street address

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

City

Urmia

Province

West Azarbaijan

Postal code

5715789397

Phone

+98 44 3346 9931

Fax

+98 44 3345 7277

Email

hamzeh.f@umsu.ac.ir

Web page address

http://Imam.umsu.ac.ir

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

City

Urmia

Province

West Azarbaijan

Postal code

5718748983

Phone

+98 44 3237 5907

Email

sabergholizadeh@yahoo.com

Web page address

http://umsu.ac.ir

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

Street address

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

City

Urmia

Province

West Azarbaijan

Postal code

5718748983

Phone

0044 3237 5907

Email

hamzeh.f@umsu.ac.ir

Web page address

<http://Imam.umsu.ac.ir>

Person responsible for scientific 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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Web page address

<http://Imam.umsu.ac.ir>

Person responsible for updating data

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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Province

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+98 44 3237 5907

Email

hamzeh.f@umsu.ac.ir

Web page address

<http://Imam.umsu.ac.ir>

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