

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of coagulation effects of tranexamic acid on bleeding rate in patients undergoing surgery for cerebral supratentorial tumors

Protocol summary

Study aim

Evaluation of coagulation effects of tranexamic acid on bleeding rate in patients undergoing surgery for cerebral supratentorial tumors

Design

A clinical trial with parallel groups, double-blind, randomized, phase 2 on 60 patients, the lottery method will be used for randomization.

Settings and conduct

The present study will be conducted as a double-blind clinical trial (patients and outcome evaluator) randomized in Imam Hossein and Shahada hospitals in Tajrish.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age over 16 years; The need for surgery for supratentorial brain tumors. Exclusion criteria: the existence or a history of diseases such as digestive disorders, heart diseases, kidney failure, coagulation disorders, medication sensitivity, thromboembolism.

Intervention groups

In group A, after induction of general anesthesia and before skin incision, a dose of 20 mg / kg of transamic acid is injected and to induce anesthesia, midazolam (0.2-0.5 mg / kg), fentanyl (4-5 micrograms / kg) are injected. Cis atracurium (0.2 mg / kg), lidocaine (1 mg / kg) and propofol anesthetic (2 mg / kg) will be used. The maintenance dose injection will continue until the skin is completely closed. In group B, after induction of general anesthesia and before cutting the skin, a single dose of 20 mg / kg of tranxamic acid is injected and after the initial loading dose, the amount of 3 mg / kg / hour of tranxamic acid will be injected until Complete skin closure will continue.

Main outcome variables

Hematocrit; Bleeding volume

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190202042588N3**

Registration date: **2022-10-24, 1401/08/02**

Registration timing: **registered_while_recruiting**

Last update: **2022-10-24, 1401/08/02**

Update count: **0**

Registration date

2022-10-24, 1401/08/02

Registrant information

Name

Sara Salarian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2665 1601

Email address

sarasalarian@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-22, 1401/04/01

Expected recruitment end date

2023-06-22, 1402/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of coagulation effects of tranexamic acid on bleeding rate in patients undergoing surgery for cerebral supratentorial tumors		Secondary Ids empty
Public title Evaluation of coagulation effects of tranexamic acid in patients undergoing surgery for cerebral supratentorial tumors		Ethics committees
Purpose Treatment		<u>1</u>
Inclusion/Exclusion criteria Inclusion criteria: All surgeries for supratentorial tumors Age over 16 years Discontinue drugs that cause coagulation disorders Women in non-pregnant status Exclusion criteria: history of coagulation disorders history of gastrointestinal disease history of liver disease history of heart disease history of renal failure (creatinine clearance less than 70min / mL, oliguria or dialysis 28 days before surgery) history of diabetes history of hypersensitivity disorders to ibuprofen, aspirin, nonsteroidal anti-inflammatory drugs, COX-2 inhibitors history of asthma long-term use of anticonvulsant drugs smoking		Ethics committee Name of ethics committee Ethics committee of Shahid Beheshti University of Medical Sciences Street address Shahid Arabi St., Yemen St., Shahid Chamran Highway City Tehran Province Tehran Postal code 1985717443
Age From 16 years old		Approval date 2022-03-08, 1400/12/17
Gender Both		Ethics committee reference number IR.SBMU.MSP.REC.1400.797
Phase 2		Health conditions studied
Groups that have been masked - Participant - Outcome assessor		<u>1</u> Description of health condition studied supratentorial brain tumor ICD-10 code D33.0 ICD-10 code description Benign neoplasm of brain, supratentorial
Sample size Target sample size: 60		Primary outcomes
Randomization (investigator's opinion) Randomized		<u>1</u> Description Hematocrit Timepoint Before surgery and one day after surgery Method of measurement Blood sampling
Randomization description For this purpose, random allocation (lottery method) will be used. For this purpose, the letter A (drug identifier) will be written on 30 sheets of paper, and all letters B will be written on the other 30 papers. It is closed and placed inside the box, then the papers will be randomly removed from the box for each patient without replacement, and the created sequence will be recorded.		<u>2</u> Description Bleeding volume Timepoint during surgery Method of measurement Direct and visual measurement
Blinding (investigator's opinion) Double blinded		Secondary outcomes empty
Blinding description The different doses of the drug will be completely similar, and the nurse will not know about the drug dose, and the patient will not know about the drug dose or whether it is a placebo, and after testing, the patients' information will be delivered to the analyzer in two groups with numbers one and two.		
Placebo Not used		
Assignment Parallel		
Other design features		

Intervention groups

1

Description

Intervention group: In group A, after induction of general anesthesia and before incision of the skin, a dose of 20 mg / kg of transamic acid is injected after the initial loading dose. The dose of 1 mg / kg / h will also be injected as a maintenance dose throughout the surgery and in a continuous infusion. The maintenance dose will be injected until the skin is completely closed.

Category

Treatment - Drugs

2

Description

Intervention group: In group B, after induction of general anesthesia and before cutting the skin, a single dose of 20 mg / kg of tranxamic acid is injected and after the initial loading dose, 3 mg / kg / h of tranxamic acid will be injected until Complete skin closure perseveranceWill find.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein Hospital

Full name of responsible person

Sara Salarian

Street address

Shahid Madani Street, Imam Hossein Square

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Tehran

Province

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2

Recruitment center

Name of recruitment center

Shohadaye Tajrish Hospital

Full name of responsible person

Noor Mohammad Arefian

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

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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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Seyed Bashir Mirtajani

Position

Researcher

Latest degree

Ph.D.

Other areas of specialty/work

Medical Genetics

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Position

Assistant Professor

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Subspecialist

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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