

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

assessment of the effect of tranexamic acid on intraoperative blood loss in patients undergoing craniotomy for tumor excision

Protocol summary

Summary

To conduct the study, 50 patients with age range of 18 to 60 years, ASA class 1 or 2, who are candidates for surgery to remove a brain tumor, will be enrolled in the study. Patients with liver, kidney and blood disorders will be excluded from the study. The amount of hemoglobin, prothrombin time with international normalized ratio, platelet count and hematocrit will be measured. General anesthesia will be induced by 2mg/kg fentanyl and 5mg/kg thiopental. Muscular relaxation will be done by 0.5mg/kg atracurium. After Intubation of patient, carbon dioxide of the end of tidal volume and blood pressure will be monitored. Patients will be randomly assigned to one of the two groups. The TXA group will receive 15mg/kg of drug in 500 mL normal saline during 30 minutes and the saline group will receive only similar volume of normal saline. Anesthesia will be maintained by isoflurane. Ventilation parameters, will be set in order to maintain the tidal volume of carbon dioxide in 30-40 mmHg. Fluid Therapy will be managed, by prescribing colloid and crystalloid soluble. The amount of hemorrhage during surgery will be substituted by an equal volume of packed cell. An adequate substitution and also preservation of intravascular volume, will be managed by blood pressure monitoring and urine output. The amount of hemoglobin will be measured before and also 24 hours after operation. One day after operation, POD, Hb and HCT will be measured. The amount of bleeding will be compared between the two groups at the end of the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016122631573N1**

Registration date: **2017-03-21, 1396/01/01**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-03-21, 1396/01/01

Registrant information

Name

Mehdi Kiaei

Name of organization / entity

Jondishapour University of Medical Science

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Recruitment status

Recruitment complete

Funding source

Ahvaz Jundishapur University Of Medical Sciences, Ahvaz, Iran

Expected recruitment start date

2016-07-25, 1395/05/04

Expected recruitment end date

2017-01-22, 1395/11/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

assessment of the effect of tranexamic acid on intraoperative blood loss in patients undergoing craniotomy for tumor excision

Public title

assessment of the effect of tranexamic acid on intraoperative blood loss in patients who undergo the

surgery which the skull is opened in, for tumor excision

Purpose

Treatment

Inclusion/Exclusion criteria

Exclusion criteria: Patients with liver, kidney and blood disorders or with previous thrombosis disease; poses of bleeding disorders; abnormal coagulation parameters (prothrombin time and platelet count) ; systolic blood pressure more than 185 on the day of surgery; the patients who were taking aspirin or any kind of anticoagulant a week before the surgery; patients who had history of intracranial arteries surgery and also patients who their surgery will take 3 to 6 hours, will be excluded from study. Inclusion criteria: Brain Tumor; age range of 18 to 60 years; ASA class 1 or 2.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ahvaz Jundishapur University Of Medical Sciences,
Ahvaz, Iran

Street address

Ahvaz Jundishapur University Of Medical Sciences,
Golestan Ave.

City

Ahvaz

Postal code

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

IR.AJUMS.REC.1395.510

Health conditions studied

1

Description of health condition studied

brain tumor

ICD-10 code

G94.8

ICD-10 code description

Other specified disorders of brain in diseases classified elsewhere

Primary outcomes

1

Description

The amount of intraoperative bleeding

Timepoint

Every hour after the intervention

Method of measurement

Through suction container, the number of blood gases and also blood surgical field

Secondary outcomes

1

Description

Comparing EBL between the group which receives TXA and the control group, in patients undergoing craniotomy for tumor excision.

Timepoint

27 hours after the intervention

Method of measurement

Based on hemoglobin levels and by formulation

2

Description

Comparing the number of consumed packed cells , between the group which receives TXA and the control group, in patients undergoing craniotomy for tumor excision.

Timepoint

3-8 hours after the intervention

Method of measurement

counting the number of packed cells

3

Description

Comparing the amount of bleeding in mL, between the group which receives TXA and the control group, in patients undergoing craniotomy for tumor excision.

Timepoint

Every hour after the intervention

Method of measurement

Through suction container, the number of blood gases and also blood surgical field

Intervention groups

1

Description

Control group: Placebo is injected to the patients of this group. Twenty five Patients with brain tumor, age range of 18 to 60 years and ASA class 1 or 2 are in this group. Saline group will receive 15mg/kg of saline. At the end, the amount of bleeding will be measured.

Category

Treatment - Drugs

2

Description

Intervention group : Assessment of the effect of Tranexamic acid on intraoperative blood loss , is the purpose. Tranexamic acid will be injected to 25 Patients with brain tumor , age range of 18 to 60 years and ASA class 1 or 2 . The TXA group will receive 15mg/kg of drug in 500 mL normal saline during 30 minutes. At the end, the amount of bleeding will be measured.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan Hospital

Full name of responsible person

Dr. Mahdi Kiaei

Street address

Golestan Hospital, Golestan Ave

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz Jundishapur University Of Medical Sciences,
Ahvaz, Iran

Full name of responsible person

Pardis Vakili

Street address

Ahvaz Jundishapur University Of Medical Sciences,
Golestan Ave.

City

Ahvaz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ahvaz Jundishapur University Of Medical Sciences,

Ahvaz, Iran

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Ahvaz Jundishapur University Of Medical Sciences,
Ahvaz, Iran

Full name of responsible person

Pardis Vakili

Position

Nutritionist

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty