

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 2026

### the effect of systemic and local injection of tranxamic acid on blood loss and need to transfusion in acetabulum surgery (Transverse, T Type and associated fracture)

#### Protocol summary

##### Study aim

the effect of systemic and local injection of tranexamic acid on blood loss and need to transfusion in acetabulum surgery (Transverse, T Type and associated fracture)

##### Design

randomized, blinded, controlled clinical trial with a parallel-group design of 100 patients

##### Settings and conduct

the patient who admitted to Tabriz Shohada Hospital from 2020 to 2022 Will participate in the study. Patients included in the study will be infused 1gr of TXA in 100cc N/S before surgical incision. After the surgery is completed 3gr TXA will be applied locally in the surgery field. blood loss during surgery will calculate by the number of blood-stained gases, Suction tank volume, and bleeding in the field of surgery. bleeding volume after surgery will calculate by volume of Hemovac drain in 24 and 48hr after surgery. Hb level will calculate after surgery and before discharge. All patients will receive DVT prophylaxis. All patients will undergo color doppler sonography to evaluate thrombotic complications after 3 weeks of surgery. the study will be double-blinded with the patient and caregiver(surgeon and radiologist). they will not be aware of the treatment of the groups

##### Participants/Inclusion and exclusion criteria

Patients over 18 years with acetabular fractures except for patients with a history of tranexamic acid allergy, thrombolytic disease, congenital coagulopathy, and preoperative massive transfusion

##### Intervention groups

This study will investigate the effect of the TXA on control of bleeding and the need for transfusion in case and control groups

##### Main outcome variables

hemoglobin level! transfusion! deep vein thrombosis! bleeding volume

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20191208045664N1**

Registration date: **2019-12-19, 1398/09/28**

Registration timing: **prospective**

Last update: **2019-12-19, 1398/09/28**

Update count: **0**

##### Registration date

2019-12-19, 1398/09/28

##### Registrant information

##### Name

Aliasghar Tanha

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 3608 0425

##### Email address

tanha\_med@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-01-21, 1398/11/01

##### Expected recruitment end date

2022-01-21, 1400/11/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

the effect of systemic and local injection of tranxamic acid on blood loss and need to transfusion in acetabulum surgery (Transverse, T Type and associated fracture)

## Public title

effect of tranxamic acid on blood loss and need to transfusion in pelvic surgery

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

patient over 18 year's old with T Type, Transverse and associated acetabular fracture

### Exclusion criteria:

sensitive to tranxamic acid history of thrombotic disease coagulopathy disorder renal and hepatic function disorder patient with multi fracture who need multiple surgery history of CVA history of coronary stent Patients treated with anticoagulants massive transfusion before surgery sensitive to drugs patients treat with anticoagulats

## Age

From **18 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

- Participant
- Care provider

## Sample size

Target sample size: **100**

## Randomization (investigator's opinion)

Not randomized

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

In this study, clinical caregivers and patients participating in the study will be blind. All patients will be aware of the benefits and potential consequences of clinical trial, but They will be unaware about who will receive the intervention. All patients will be treated by a surgeon and he will be blind about tranexamic acid order. Tranexsamic acid transfusion will be administered just before surgery by an anesthesiologist. Topical injection will be applied to all patients in 30 cc solution at the end of surgery. some of them will receive placebo(normal saline solution). after 3 week of surgery, patients will be evaluated for vascular thrombosis by color Doppler ultrasound by a Radiologist. He will not be aware of the group who give intervention.

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

##### Street address

Shohada Hospital, Golshahr, Baharestan, Tabriz

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5733395193

#### Approval date

2019-12-08, 1398/09/17

#### Ethics committee reference number

IR.TBZMED.REC.1398.946

## Health conditions studied

### 1

#### Description of health condition studied

Acetabulum fracture

#### ICD-10 code

S32.4

#### ICD-10 code description

Fracture of acetabulum

## Primary outcomes

### 1

#### Description

hemoglobin level

#### Timepoint

before surgery, 24 and 48he after surgery

#### Method of measurement

with automatic cell counter in laboratory

### 2

#### Description

deep vein thrombosis

#### Timepoint

3 weeks after surgery

#### Method of measurement

with color doppler sonography by the radiologist

### 3

#### Description

bleeding volume

#### Timepoint

during and after surgery

#### Method of measurement

The volume of the suction tank, the number of gases-stained with blood, and bleeding of the surgery field. volume of the hemovak drain after surgery

#### 4

##### Description

Blood transfusion

##### Timepoint

Before surgery; after 24 and 48hr of surgery

##### Method of measurement

According to Hb level

### Secondary outcomes

empty

### Intervention groups

#### 1

##### Description

Intervention group: Before surgical excision of this group, they will be infused with 1 gram of tranexamic acid dissolved in 100 ml of normal saline. 3 grams of tranexamic acid dissolved in 30 cc normal saline is applied topically at the site of surgery after the end of surgery.

##### Category

Treatment - Drugs

#### 2

##### Description

Control group: The control group received no injection of tranexamic acid and The placebo will use in the field of surgery

##### Category

Treatment - Drugs

### Recruitment centers

#### 1

##### Recruitment center

###### Name of recruitment center

Shohada Hospital

###### Full name of responsible person

Aliasghar Tanha

###### Street address

Shohada Hospital, Baharestan Ave, Golshahr, Tabriz

###### City

Tabriz

###### Province

East Azarbaijan

###### Postal code

3395193573

###### Phone

+98 21 3608 0425

###### Email

Tanha\_med@yahoo.com

### Sponsors / Funding sources

#### 1

##### Sponsor

###### Name of organization / entity

Tabriz University of Medical Sciences

###### Full name of responsible person

Alireza Sadeghpour Teimorloei

###### Street address

Shohada Hospital, Baharestan Ave, Golshahr, Tabriz

###### City

Tabriz

###### Province

East Azarbaijan

###### Postal code

3395193573

###### Phone

+98 41 3389 3336

###### Email

sadeghpoura46@yahoo.com

##### Grant name

##### Grant code / Reference number

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

No

##### Title of funding source

Tabriz university of medical science

##### 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

Aliasghar Tanha

###### Position

Orthopedic residency

###### Latest degree

Medical doctor

###### Other areas of specialty/work

Orthopedics

###### Street address

Shohada hospital, baharestan, golshahr, il goli, tabriz

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###### Province

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**Email**

Tanha\_med@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Aliasghar Tanha

**Position**

Orthopedic residency

**Latest degree**

Medical doctor

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## Person responsible for updating data

### Contact

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Tabriz University of Medical Sciences

**Full name of responsible person**

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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

Yes - There is a plan to make this available

### Analytic Code

Not applicable

### Data Dictionary

Not applicable

### Title and more details about the data/document

After the study, all data will be shared after unidentifiable individuals

### When the data will become available and for how long

after 6 months of publication, data will be accessible

### To whom data/document is available

The study data will be available only to researchers working in academic institutions

### Under which criteria data/document could be used

Due to the unrecognizable people, no restrictions will apply

### From where data/document is obtainable

Aliasghar Tanha Phone Number: 00989127940833 Email: Tanha\_med@yahoo.com

### What processes are involved for a request to access data/document

After making a call and stating the reason for the need for data, he will be provided with the requested items between 1-2 weeks

### Comments