Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 transfuion
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
City
Tabriz
Province
East Azarbaijan
Postal code
3395193573
Phone

+98 21 3608 0425

Fax

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

Other areas of specialty/work

Orthopedics

Street address

Shohada hospital, baharestan, golshahr, il goli, tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

3395193573

Phone

+98 21 3608 0425

Fax

Email

Tanha_med@yahoo.com

Person responsible for updating data

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

City

Tabriz

Province

East Azarbaijan

Postal code

3395193573

Phone

+98 21 3608 0425

Fax

Email

Tanha_med@yahoo.com

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