Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effect of Intravenous Tranexamic Acid on blood loss in Pelvic and Acetabular fractures in patients referred to Taleghani and Emam Hosein Hospital of Tehran between 2019-2020

Protocol summary

Study aim
Effect of Intravenous Tranexamic Acid on blood loss in pelvic and acetabular fractures

Design
A parallel group, double blind, randomized clinical trial consisting 108 patients. Random function in excel will be used to randomize the patients.

Settings and conduct
The study will be conducted on patients referred to Taleghani and Emam Hosein hospital in Tehran diagnosed with pelvic or acetabular fractures due to trauma. First of all patients will be randomized with random function in Excel into Intervention and control groups. The intervention group will receive 15 milligram/kilogram of Tranexamic Acid in 500 milliliters of normal saline 30 minutes before surgery intravenously. The control group will receive equivalent volume of normal saline 30 minutes before surgery. In this study patients and analyzer will be triple-blind. Medical data will be gathered by medical documents and the questionnaires filled out by patients.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1-Pelvic fracture 2-Acetabular fracture
Exclusion criteria: 1-Age below 18 years old

Intervention groups
Case group will receive 15 milligram/kilogram Intravenous Tranexamic Acid in normal saline. Control group will receive equal volume of normal saline

Main outcome variables
blood loss; used packed cell(s); Estimated blood loss; age; gender; Body Mass Index(BMI); History of Coronary Artery diseases; History of diabetes; pre-operation hemoglobin level; post-operation hemoglobin level; weight of blood soaked gauze pads used during the surgery; history of hypertension; Duration of surgery; blood drained during first post-op 24 hours; confirmed symptomatic Deep Vein Thrombosis(DVT); incidence of Pulmonary ThromboEmbolism(PTE); Site of fracture(s); Type of fracture(s);Duration between occurrence of fracture and start of surgery; Post-op hospitalization days

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180404039188N2**
Registration date: **2021-05-10, 1400/02/20**
Registration timing: **retrospective**

Last update: **2021-05-10, 1400/02/20**
Update count: **0**

Registration date
2021-05-10, 1400/02/20

Registrant information

Name
Reza Zandi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 2243 2560

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-03-21, 1398/01/01

Expected recruitment end date
2021-03-19, 1399/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of Intravenous Tranexamic Acid on blood loss in Pelvic and Acetabular fractures in patients referred to Taleghani and Emam Hosein Hospital of Tehran between 2019-2020

Public title
Effect of Tranexamic Acid on blood loss in Pelvic and Acetabular fractures
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with pelvic fractures Patients with acetabular fractures
Exclusion criteria:
Age below 18
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **108**
Randomization (investigator's opinion)
Randomized
Randomization description
The randomization for 2 groups (1 Control, and 1 intervention groups), will done using software, 54 random numbers for each group. The surgeon can not play a role in predicting treatment of the disease, and choosing the type of treatment. Random sequence will generate by software. All admitted patients will be placed in one of the groups according to the pre-determined code
Blinding (investigator's opinion)
Double blinded
Blinding description
Allocation concealment was assured using opaque, sealed envelopes. The anesthesia technician received the envelope and administered either tranexamic prior to the procedure. The patient was given general anesthesia and was unaware of the received treatment and remained blinded after surgery. Two envelopes with the same information about treatment allocation were created. The second envelope was given to the nurse for postoperative drug administration.
Placebo
Not used
Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahid Beheshti University of medical sciences
Street address
Koodakyar deadend, Daneshjou Boulevard, Yaman street, Shahid Chamran Highway
City
Tehran
Province
Tehran
Postal code
1985717443
Approval date
2020-09-23, 1399/07/02
Ethics committee reference number
IR.SBMU.MSP.REC.1399.275

Health conditions studied

1

Description of health condition studied
Fracture of acetabulum
ICD-10 code
S32.40
ICD-10 code description
Unspecified fracture of acetabulum

2

Description of health condition studied
Fracture of pelvis
ICD-10 code
S32.9
ICD-10 code description
Fracture of unspecified parts of lumbosacral spine and pelvis

Primary outcomes

1

Description
Estimated blood loss during surgery
Timepoint
End of surgery
Method of measurement
Estimated Blood Loss(in milliliter)=1000*((hemoglobin level before sugery - hemoglobin after surgery) * total body volume + transfused allogeneic hemoglobin)

2

Description
Post-op drained blood
Timepoint
Last day of hospitalization
Method of measurement
Perception and by using drainage bag

Secondary outcomes

1

Description
vein thrombosis of lower limb
Timepoint
three months
Method of measurement
color doppler ultrasonography if patient has related symptoms

2

Description
Pulmonary embolism
Timepoint
three months
Method of measurement
Lung CT angiography if patient has related symptoms

3

Description
Drug-associated reaction
Timepoint
three months
Method of measurement
Questionnaire based on drug-associated reaction symptoms answered by patient

Intervention groups

1

Description
Intervention group: Intervention group will receive 15 milligrams per kilogram intravenous tranexamic acid dissolved in 500 milliliters of normal saline 30 minutes prior to start of surgery.
Category
Treatment - Drugs

2

Description
Control group: Control group will receive equivalent volume of normal saline 30 minutes prior to start of surgery.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Taleghani hospital
Full name of responsible person
Reza Zandi
Street address
Aarabi street-Yaman street-Shahid Chamran highway
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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
Shahid Beheshti University of Medical Sciences, Yemen St., Arabi St., Chamran highway.
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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
Reza Zandi

Position
Associate Professor

Latest degree
Subspecialist

Other areas of specialty/work
Orthopedics

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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
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
The data including age, gender, history of diseases (Coronary artery disease, diabetes and Hypertension) and other considered variable will be shared after deidentification.

When the data will become available and for how long
Data will be available in 6 months after publication.

To whom data/document is available
People working in academic institutions

Under which criteria data/document could be used
Any type of analysis is prohibited unless the person in charge of the research is informed and would permit.

From where data/document is obtainable
Reza Zandi Address: Aarabi St. - Yaman St. - Shahid Chamran Highway - Tehran Email: reza.zandi@sbmu.ac.ir

What processes are involved for a request to access data/document
Doing the letter writing accordance with the person in charge of the research

Comments