Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jun 2026

The effect of intravenous Tranexamic acid on postoperative bleeding in patients with shaft femoral fractures

Protocol summary

Study aim
Evaluation effect of intravenous Tranexamic acid on postoperative bleeding in patients with shaft femoral fractures

Design
The study will be double blind and clinical trial.60 patients will be randomly divided into 2 groups. The groups are parallel. The trial phase is 3

Settings and conduct
Patients candidate for surgery of shaft femoral fractures in valiasr Hospital in Arak are divided into 2 groups by simple randomization with blocks.The study is double-blind in which outcome evaluator and data analyst and participant are kept blind.

Participants/Inclusion and exclusion criteria
Inclusion criteria: All patients who are candidates for shaft and distal femoral fractures, lack of sensitivity to tranexamic acid, surgery that lasts less than 3 hours Exclusion criteria: underlying diseases such as kidney disease, history of myocardial ischemia, hypertension, history of cerebral ischemia, history of thromboembolism, anemia, take any anticoagulants for 5 days before surgery, hematuria, platelets less than 150,000 before surgery

Intervention groups
In the intervention group, before the start of surgery, 10 milligram in kilogram of tranexamic acid (Tranexip in Iran -Caspian Company, 100 milligram in kilogram) will be given by slow intravenous injection with vital signs and standard monitoring careful control. In the control group, they will receive the same amount intravenously before starting placebo surgery (normal saline).

Main outcome variables
Bleeding amount, hemoglobin amount, hematocrit amount, mortality

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211208053326N1**
Registration date: **2022-01-30, 1400/11/10**
Registration timing: **registered_while_recruiting**

Last update: **2022-01-30, 1400/11/10**
Update count: **0**

Registration date
2022-01-30, 1400/11/10

Registrant information

Name
Rahim Shiri

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 86 3417 4553

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raminshiri45@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-01-20, 1400/10/30

Expected recruitment end date
2023-01-20, 1401/10/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of intravenous Tranexamic acid on postoperative bleeding in patients with shaft femoral fractures

Public title
The effect of intravenous Tranexamic acid on postoperative bleeding in patients with shaft femoral fractures
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All patients who are candidates for shaft and distal femoral fractures Lack of sensitivity to tranexamic acid No history of cerebral ischemia Lack of hematuria Surgery that lasts less than 3 hours
Exclusion criteria:
hypertension history of cerebral ischemia anemia take any anticoagulants for 5 days before surgery platelets less than 150,000 before surgery history of myocardial ischemia underlying diseases such as kidney disease
Age
No age limit
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be allocated into 3 groups using a permuted balanced block randomization method with the size of blocks 4 and 8. Random sequence will be generated by an epidemiologist by running an online program in sealed envelope website (https://www.sealedenvelope.com/). Random chain concealment is done by opaque envelope method.
Blinding (investigator's opinion)
Double blinded
Blinding description
The study is double-blind. The analysis is done by the analyzer and outcome evaluator and the participant. analyzer, evaluators, and participants are unaware of the consequences of grouping. The Resident is unaware of the drugs prescribed in each group and the orthopedic specialist prescribes the drug. Patients also do not know their group.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics comittee of Arak University of Medical Sciences
Street address
Ethics comittee, Research center, Payambar Azam complex, Basij squre ,Sardasht,Arak
City
Arak
Province
Markazi
Postal code
3848176941
Approval date
2021-11-17, 1400/08/26
Ethics committee reference number
IR.ARAKMU.REC.1400.233

Health conditions studied

1

Description of health condition studied
shaft femoral fractures
ICD-10 code
S72.3
ICD-10 code description
Fracture of shaft of femur

Primary outcomes

1

Description
Bleeding amount
Timepoint
From 6 hours and 24 hours after surgery
Method of measurement
Millilitre

2

Description
Hemoglobin amount
Timepoint
Before and after surgery
Method of measurement
Blood test

3

Description
Hematocrit amount
Timepoint
Before and after surgery
Method of measurement
Blood test

4

Description
Mortality
Timepoint
End of study
Method of measurement
Observation

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Before the start of surgery, 10 milligram in kilogram of tranexamic acid (Tranexip in Iran -Caspian Company, 100 milligram in kilogram) will be given by slow intravenous injection with vital signs and standard monitoring careful control.
Category
Treatment - Drugs

2

Description
Control group: In the control group, they will receive the same amount intravenously before starting placebo surgery (normal saline).
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Valiasr hospital
Full name of responsible person
Dr Mohsen Parsi khameneh
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Arak 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
Arak University of Medical Sciences
Full name of responsible person
Dr Mohsen Parsi Kameneh
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

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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