Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jun 2026

Investigating the effect of local, oral and intravenous tranexamic acid on the amount of bleeding during humerus fracture surgery

Protocol summary

Study aim
Investigating the effect of local, oral and intravenous tranexamic acid on the amount of bleeding during humerus fracture surgery

Design
The study will be double blind and clinical trial.90 patients will be randomly divided into 3 groups. The groups are parallel. The trial phase is 3.

Settings and conduct
Patients with humerus fracture surgery in valiasr Hospital in Arak are divided into 3 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 with ASA class 1 and 2, all patients with humerus fracture, all patients candidates for elective surgery, 18 to 70 years, patients with BMI greater than 30. Exclusion criteria: pregnancy, underlying kidney, heart, lung and liver disease, candidate patients for general anesthesia; sensitivity to tranexamic acid, no consent to participate in the study.

Intervention groups
Intervention group 1: patients will receive 20 mg/kg tranexamic acid IV. Intervention group 2: Patients receive 1 gram of tranexamic acid orally 1 hour before surgery with 1 glass of water. Intervention group 3: 3 grams of topical tranexamic acid will be placed in contact with the operation site.

Main outcome variables
Bleeding

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20141209020258N184**
Registration date: **2023-05-29, 1402/03/08**
Registration timing: **prospective**

Last update: **2023-05-29, 1402/03/08**
Update count: **0**

Registration date
2023-05-29, 1402/03/08

Registrant information

Name
Fariba Farokhi

Name of organization / entity
Arak University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-06-05, 1402/03/15

Expected recruitment end date
2024-06-04, 1403/03/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of local, oral and intravenous tranexamic acid on the amount of bleeding during humerus fracture surgery

Public title
Investigating the effect of local, oral and intravenous

tranexamic acid on the amount of bleeding during humerus fracture surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All patients with ASA class 1 and 2 All patients with humerus fracture All patients candidates for elective surgery 18 to 70 years Patients with BMI greater than 30 Patients candidate for general anesthesia

Exclusion criteria:

Pregnancy Underlying kidney, heart, lung, and liver disease Sensitivity to tranexamic acid No consent to participate in the study

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be allocated into3 groups using a permuted balanced block randomization method with the size of blocks 6. 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

In this study, the supervisor knows about the grouping and prescribes the drugs for the patients, and the specialized assistant does not know about the prescribed drugs, and the follow-up of the patients is with the orthopedic assistant, and the analyst does not know about the grouping, and as a result, the study will be double-blind.

Placebo

Not 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

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Province

Markazi

Postal code

3848176941

Approval date

2023-05-07, 1402/02/17

Ethics committee reference number

IR.ARAKMU.REC.1402.036

Health conditions studied

1

Description of health condition studied

Humerus fracture

ICD-10 code

M80.02

ICD-10 code description

Age-related osteoporosis with current pathological fracture, humerus

Primary outcomes

1

Description

Bleeding

Timepoint

During the operation, recovery and 24 and 48 hours after the operation

Method of measurement

Physical examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: patients will receive 20 mg/kg tranexamic acid IV.

Category

Treatment - Drugs

2

Description

Intervention group 2: Patients receive 1 gram of tranexamic acid orally 1 hour before surgery with 1 glass

of water.

Category
Treatment - Drugs

3

Description
Intervention group 3: 3 grams of topical tranexamic acid will be placed in contact with the operation site.

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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Full name of responsible person
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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 Khameneh

Position
Assistant professor

Latest degree
Specialist

Other areas of specialty/work
Orthopedics

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Specialist

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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