Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of femoral shaft fracture bleeding in the two methods of Tranexamic acid and controled hypotension

Protocol summary

Summary

The study aims: to reduce bleeding in major surgery.It is a blind study. Study of population: 60 orthopedic patients who need to have this surgery and are elective . Inclusion criteria for femoral shaft fractures are first time, non-emergency, aged 60-18 years and exclusion criteria are prohibition tranexamic acid and hypotension. In the first group of controlled hypotension using nitroglycerin during anesthesia and mean arterial pressure of 60 mmHg and 90-80 mmHg for systolic pressure is brought and in the second group that are normotensive, half hour before and after the anesthetic tranexamic acid is injected and Systolic arterial blood pressure is maintained in the range 130-120 and outside of this measures the medical therapy is performed and the patient is excluded of this study. All the patients are under general anesthesia.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201111198131N1**
Registration date: **2012-02-27, 1390/12/08**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-02-27, 1390/12/08

Registrant information

Name

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Name of organization / entity

Tehran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for reseach, Tehran University of Medical Sciences

Expected recruitment start date

2010-03-21, 1389/01/01

Expected recruitment end date

2011-10-22, 1390/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of femoral shaft fracture bleeding in the two methods of Tranexamic acid and controled hypotension

Public title

Tranexamic acid in reducing bleeding in the femoral shaft fracture surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: femoral shaft fracture; the first time; non-emergency; age 60-18 years; Normotensive being; tourniquet is not used; the amount of Hgb in the range of 12-10; following a period of 3 hours. Exclusion criteria: prohibition hypotension (eg, cardiovascular disease); previous use of anticoagulants; unexpected factors that complicate or prolong the surgery; to be with multiple trauma; hypertensive patients; reintroduction; diseases that cause clotting disorders; including banning the use of tranexamic acid.

Age
From **18 years** old to **65 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tehran University of Medical Sciences
Street address
Pursina street, 16 Azar street
City
Tehran
Postal code
Approval date
2010-04-13, 1389/01/24
Ethics committee reference number
42112

Health conditions studied

1

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

Primary outcomes

1

Description
The amount of bleeding
Timepoint
during anesthesia
Method of measurement
Counting blood gases, the suction,and operation field

Secondary outcomes

1

Description
Hypotension
Timepoint
during anesthesia
Method of measurement
by NIBP

2

Description
arhythmia
Timepoint
during anesthesia
Method of measurement
by monitoring of ECG

3

Description
sever bleeding
Timepoint
during anesthesia
Method of measurement
The number of blood gas , Surgery field,suction

Intervention groups

1

Description
tranexamic acid injection 500 mg Two Time
Category
Treatment - Drugs

2

Description
TNG injection 5 Mic per min
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Rasul Akram hospital
Full name of responsible person
Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Vice chancellor for reseach, Dr Akbar Fotuhi
Street address
Central organization of Tehran University of Medical Sciences, Gods street, Keshavarz street
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty