Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effects of tranexamic acid in amount of bleeding in patients with pelvic trauma

Protocol summary

Study aim
Effects of tranexamic acid on bleeding volume in patients with pelvic trauma
Design
103 eligible patients with pelvic trauma referred to poursina hospital of Guilan University of Medical Sciences were chosen. Then, patients were randomly divided into two control and intervention groups. Case group received TXA and control group placebo
Settings and conduct
Poursina Hospital of Rasht, Guilan University of Medical Sciences
Participants/Inclusion and exclusion criteria
All 18-60 years old Patients with pelvic trauma who admitted in hospital in first 3 hours after accident enrolled to the study
Intervention groups
patients were randomly divided into two control and intervention groups. Patients in case group received TXA 1 g single dose. Then pulse rate, blood pressure in 24h, 48h, 72h after operation and , Hb and Hct in 24h, 48h, 72h after operation and adverse effects compared between 2 groups of case and control
Main outcome variables
Control of bleeding of Pelvic trauma

General information

Reason for update
Acronym
TXA
IRCT registration information
IRCT registration number: **IRCT20130710013947N7**
Registration date: **2018-01-12, 1396/10/22**
Registration timing: **prospective**

Last update: **2018-01-12, 1396/10/22**
Update count: **0**

Registration date
2018-01-12, 1396/10/22

Registrant information
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-01-21, 1396/11/01
Expected recruitment end date
2018-06-22, 1397/04/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effects of tranexamic acid in amount of bleeding in patients with pelvic trauma

Public title
Effects of tranexamic acid in amount of bleeding in patients with pelvic trauma
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with age 18-60 years oldAll the patients with

pelvic trauma who admitted in hospital in first 3 hours after accident

Exclusion criteria:

Patients who died during the operation or studymultitraumaAnticoagulant drugs use such as A.S.A and dipyridamole; Increased in PT, PTT, INR;History of CVA, MI, bleeding disorder, TBI, CPR, Renal Failure, OCP;Pregnancy and breastfeedingPatients received pack

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **106**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization use in this study, 1 g TXA single dose and placebo(N.S 0/9%) pulled in 60 syringes randomly by operation room technician with numbered 1 and 2 and then injected IV without authors and surgeons notice

Blinding (investigator's opinion)

Double blinded

Blinding description

Randomization use in this study, 1 g TXA single dose and placebo(N.S 0/9%) pulled in 60 syringes randomly by operation room technician with numbered 1 and 2 and then injected IV without authors and surgeons notice

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Guilan University of medical Sciences

Street address

Namjoo Street, Rasht, Guilan, Iran

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Province

Guilan

Postal code

4144666949

Approval date

2017-09-12, 1396/06/21

Ethics committee reference number

IR.GUMS.REC.1396.224

Health conditions studied

1

Description of health condition studied

Anticoagulant drugs

ICD-10 code

Y44.3

ICD-10 code description

Anticoagulant antagonists, vitamin K and other coagulants

Primary outcomes

1

Description

blood loss

Timepoint

24hT 48h and 72 h

Method of measurement

based on blood pressure, Hb, Hct, Pulse rate

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: will receive TXA 1for single dose

Category

Treatment - Drugs

2

Description

Control group: will receive placebo

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Poursina hospital of Rasht, Guilan University of Medical Sciences

Full name of responsible person

Dr Vahid Monsef

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Sponsors / Funding sources

1

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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
Rasht 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
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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
All data will published as article in journal without patients name
When the data will become available and for how long
After publication in journal
To whom data/document is available
It will be free or not depend on journal policy
Under which criteria data/document could be used
It will be free or not depend on journal policy
From where data/document is obtainable
It will be free or not depend on journal policy
What processes are involved for a request to access data/document
It will be free or not depend on journal policy
Comments
It will be free or not depend on journal policy