

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of two doses of tranexamic acid on reducing of bleeding during spinal fusion surgery

Protocol summary

Summary

The effect of tranexamic acid in reducing of bleeding during and after spinal fixation surgery is the aim of this study. the study is a double blind clinical trial with placebo group. the Population of this study are the patients aged 18 to 60 years old with ASA class 1 and 2 admitted for spinal fixation surgery. patients with history of thromboemboly and vascular disease and consumption of anticoagulant drugs have been excluded from study. 102 patients evaluated in 3 groups. for the first and second group 10 mg/kg tranexamic acid as bolus dose of drug is infused before skin incision. for the second group maintenance dose of tranexamic acid 1 mg/kg/hour continued during surgery. for the third group normal saline as a placebo is infused. this is expected that the amount of bleeding during surgery by following administration of tranexamic acid will be reduced and this reduction will be more in patients who have recieved maintenance infusion of tranexamic acid . thus blood transfusion to patients and complications of transfusion are prevented.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015101924601N1**

Registration date: **2015-11-29, 1394/09/08**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-11-29, 1394/09/08

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of Ardabil University of Medical Sciences

Expected recruitment start date

2015-11-06, 1394/08/15

Expected recruitment end date

2016-03-05, 1394/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of two doses of tranexamic acid on reducing of bleeding during spinal fusion surgery

Public title

The effect of tranexamic acid on reducing of bleeding during spinal fixation surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: the patients aged beetween 18 and 60 years old with class ASA 1 and 2 (american anesthesia society) that admitted for spinal fixation surgery.

Exclusion criteria: the patient's Dissatisfaction.the patients with thrombotic diseases. the use of antithrombotic drugs. history of cardiovascular and

cerebral disease. hypertention. deep vein thrombosis. pulmonary emboli. peripheral vascular disease. pregnant and lactating women and history of allergy to tranexamic acid

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **102**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee Ardabil University of Medical Sciences

Street address

Ardabil University of Medical Sciences, Shool of Medicine, Daneshgah Street

City

Ardabil

Postal code

5618953141

Approval date

2015-10-04, 1394/07/12

Ethics committee reference number

IR.ARUMS.REC.1394.51

Health conditions studied

1

Description of health condition studied

The effect of two different form Tranexamic Acid administration for bleeding reduction at spinal fixation surgery

ICD-10 code

D69.9

ICD-10 code description

Haemorrhagic condition, unspecified

Primary outcomes

1

Description

The volume of bleeding due to surgery

Timepoint

The end of surgery and 24 hours later

Method of measurement

The volume of blood in suction after reducing washing serum and scale of bloody guases by digital scale

2

Description

the volume of blood transfused to patient

Timepoint

at the surgery time untill 24 hours later

Method of measurement

the amount of pack cell transfused

Secondary outcomes

1

Description

Hemodynamic variation

Timepoint

Before anesthesia and then every 30 minuets

Method of measurement

Noninvasive digital blood pressure monitor and pulseoximetry

2

Description

Complication due to drug(nausea. vomitting. abdominal pain. skin reactions. DVT. pulmonary emboli. CAD. CVA)

Timepoint

The end of surgery in recovery and 24 hours later in hospitalization wards

Method of measurement

Visit and interview with patients

3

Description

Surgery duration

Timepoint

From incison of skin till end of skin suture

Method of measurement

To minute

Intervention groups

1

Description

Infusion 10 mg/kg of tranexamic acid by microset with total volume of 100 cc during 10 minutes before skin

incision and continued with 20 drop/ min of normal saline as placebo

Category
Treatment - Drugs

2

Description
Infusion 10 mg/kg of tranexamic acid by microset with total volume of 100 cc during 10 minutes before skin incision and continued by 1 mg/kg/hour drug infusion untill end of surgery

Category
Treatment - Drugs

3

Description
control group: infusion of 100 cc normal saline during 10 minutes and continued infusion with 20 drop/min untill end of surgery as placebo

Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Fatemi Hospital
Full name of responsible person
Ali Mohammadian Erdi, Associate Professor of Anesthesia
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Fatemi Hospital, Shariati Square, Ardabil
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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
Vice Chancellor for Research of Ardabil 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

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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