

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparison of the effect of tranexamic acid and Dexmedetomidine on the amount of bleeding during Spinal posterior fusion surgery

Protocol summary

Study aim

Comparison of the effect of tranexamic acid and dexmedetomidine on the amount of bleeding in posterior spinal fusion surgery

Design

A randomized clinical trial with parallel groups, double-blind, phase 3 on 90 patients. Random allocation of samples to study groups is performed by block randomization method and by using sas 9.4 software.

Settings and conduct

This double-blind clinical trial study will be performed on 90 patients undergoing spinal posterior fusion surgery (in intervention group 1 and intervention 2) in Ayatollah Mousavi Hospital in Zanjan. Random allocation of samples is done by block method and using statistical software. The Boazaart scale will be used to measure the amount of bleeding during the surgery.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18-60 years, American Society of Anesthesiologists Class (ASA Class) I & II Exclusion criteria: Drug addiction, Liver and kidney failure, Diabetes, Heart and lung diseases, Coagulation disorders, History of allergies to study drugs, Pregnancy in women, Heart disease includes bradycardia, uncontrolled blood pressure, and AV block II & III, Acute cerebrovascular conditions

Intervention groups

Patients in intervention group 1, before surgery and after induction of anesthesia, receive tranexamic acid (manufactured by Caspian Tamin) with an initial dose of 15 mg/kg for 15 minutes followed by a maintenance intravenous infusion of 1 mg/kg /h. Patients in intervention group 2, before surgery and after induction of anesthesia, receive dexmedetomidine (exir pharmacy) with an initial dose of 1µg/kg for 10 minutes and then with a maintenance intravenous infusion at a dose of 0.7 µg/kg/h.

Main outcome variables

The amount of bleeding during the surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200910048678N2**

Registration date: **2021-12-18, 1400/09/27**

Registration timing: **prospective**

Last update: **2021-12-18, 1400/09/27**

Update count: **0**

Registration date

2021-12-18, 1400/09/27

Registrant information

Name

seyede fatemeh gheiasi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-22, 1400/10/01

Expected recruitment end date

2022-09-23, 1401/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of tranexamic acid and Dexmedetomidine on the amount of bleeding during Spinal posterior fusion surgery Public title Comparison of the effect of tranexamic acid and dexmedetomidine on the amount of bleeding Purpose Treatment Inclusion/Exclusion criteria Inclusion criteria: Age 18-60 years American Society of Anesthesiologists Class (ASA Class) I & II Exclusion criteria: Drug addiction Liver and kidney failure Diabetes Heart and lung diseases Coagulation disorders History of allergies to study drugs Pregnancy in women Heart disease includes bradycardia, uncontrolled blood pressure, and AV block II & III Acute cerebrovascular conditions Age From 18 years old to 60 years old Gender Both Phase 3 Groups that have been masked • Participant • Investigator • Outcome assessor Sample size Target sample size: 90 Randomization (investigator's opinion) Randomized Randomization description At first, the samples enter the study in a convenience method. Then, the samples are assigned to two interventions groups 1 and 2 based on random blocks with a size of 4. Random blocks are created based on the PROC PLAN program and in SAS 9.4 software. In order to be able to match samples in terms of age and gender in each group, after the available samples are identified, samples are divided according to age and gender groups and identified in each group. Random allocation will be based on groups. The groups will be divided into two groups based on the cut-off point of 50 years: over 50 years old and under 50 years old, and in terms of gender, they will be divided into two groups, male and female. Blinding (investigator's opinion) Double blinded Blinding description Patients know that they are participating in a study that aims to evaluate the effect of tranexamic acid and dexmedetomidine on reducing intraoperative bleeding but are unaware that they are receiving tranexamic acid and dexmedetomidine. The drugs are similar in color and appearance, prepared in syringes, and coded. The anesthesiologist who injects the drug is not aware of the medication that patients receive. Placebo	Not used Assignment Parallel Other design features Secondary Ids empty Ethics committees <u>1</u> Ethics committee Name of ethics committee Ethics committee of Zanjan University of Medical Sciences Street address Vice-Chancellor for Research and Technology, 3th Floor, 2th Bldg., Zanjan University of Medical Sciences, Azadi Blvd. Zanjan, IRAN. City Zanjan Province Zanjan Postal code 4515613191 Approval date 2021-12-01, 1400/09/10 Ethics committee reference number IR.ZUMS.REC.1400.372 Health conditions studied <u>1</u> Description of health condition studied Spinal posterior fusion ICD-10 code M43.2 ICD-10 code description Fusion of spine Primary outcomes <u>1</u> Description The amount of bleeding Timepoint During surgery Method of measurement Boezaart scale Secondary outcomes empty Intervention groups
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1

Description

Patients in intervention group 2, before surgery and after induction of anesthesia, receive dexmedetomidine (exir pharmacy) with an initial dose of 1µg/kg for 10 minutes and then with a maintenance intravenous infusion at a dose of 0.7 µg/kg/h.

Category

Treatment - Drugs

2

Description

Patients in intervention group 1, before surgery and after induction of anesthesia, receive tranexamic acid (manufactured by Caspian Tamin) with an initial dose of 15 mg/kg for 15 minutes followed by a maintenance intravenous infusion of 1 mg/kg /h.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Mousavi Hospital

Full name of responsible person

Mohammad Hossein Brojerdi

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Ayatollah Mousavi Hospital, Gavazang, Zanjan, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

Dr. Alireza Shoghli

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research@zums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Zanjan 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

Zanjan University of Medical Sciences

Full name of responsible person

Hengameh Vaezi

Position

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Latest degree

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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

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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

-

When the data will become available and for how long

-

To whom data/document is available

-

Under which criteria data/document could be used

-

From where data/document is obtainable

-

What processes are involved for a request to access data/document

-

Comments

-

Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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