

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jun 2026

Comparison of the effect of oral clonidine and intravenous Tranexamic acid on bleeding control in posterior lumbar spine fusion surgery

Protocol summary

Study aim

Comparison of the effect of oral clonidine and intravenous tranexamic on bleeding control in posterior lumbar spine fusion surgery

Design

A randomized clinical trial (Sealed envelopes of the same shape and size), double-blind, without control group, in parallel groups, phase 2-3, and with the participation of 136 patients .

Settings and conduct

Candidate patients for posterior fusion surgery of the lumbar spine who refer to Loqman Hospital in Tehran during the study, if they are eligible, will be included in the study and will be randomly assigned to clonidine and tranexamic groups by randomized block method. This study will be conducted in a double-blind manner, so that the evaluator and recorder of the results and the data analyst will not know the type of intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patient satisfaction, American Society of Anesthesiology (ASA) physical class I and II, age 50-18 years, and candidate for posterior lumbar spine fusion surgery. Exclusion criteria: Hemoglobin less than 10 and suffering from hemophilia.

Intervention groups

The first group will receive clonidine 0.2 mg (oral) and the second group will receive tranexamic acid 10 mg per kilogram (injection); All medicines will be procured from Abidi Pharmaceuticals and will be prescribed to patients once. The anesthesia method will be the same for all patients.

Main outcome variables

Bleeding

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151012024493N5**

Registration date: **2023-02-17, 1401/11/28**

Registration timing: **prospective**

Last update: **2023-02-17, 1401/11/28**

Update count: **0**

Registration date

2023-02-17, 1401/11/28

Registrant information

Name

Parissa Sezari

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 912 219 4036

Email address

psezari@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-06, 1401/12/15

Expected recruitment end date

2023-08-19, 1402/05/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of oral clonidine and intravenous Tranexamic acid on bleeding control in posterior lumbar spine fusion surgery

Public title

Comparison of clonidine and tranexamic acid on the control of lumbar surgical bleeding

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

American Society of Anesthesiology (ASA) physical class I and II Candidate for posterior lumbar spine fusion surgery Patient satisfaction Age 18-50 years

Exclusion criteria:

Hemoglobin less than 10 Having hemophilia

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **136**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, people enter the study groups by lottery; In such a way that the type of injectable drug used is placed in the desired number in the sealed opaque envelopes that are coded. Each of the codes is also written on a piece of paper, folded and placed inside a box. After entering the operating room, each patient takes out one of the pieces of paper from the box. The envelope has the same number as the number inside the selected paper. which is applied to the patient. This work continues until the end of the papers so that the number of patients reaches the desired number in the groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

Medicines will be prescribed by the first researcher. The second researcher will record and evaluate the results and they will be unaware of the type of drug injected by the first researcher; Also, the coded information collection form will also be delivered to the statistical consultant; In the information collection forms, the type of medicine is not clear.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Near Ayatollah Taleghani Hospital, Shahid Arabi St, Yemen St, Shahid Chamran Highway

City

Tehran

Province

Tehran

Postal code

5981764896

Approval date

2022-01-30, 1400/11/10

Ethics committee reference number

IR.SBMU.RETECH.REC.1400.866

Health conditions studied

1

Description of health condition studied

Bleeding

ICD-10 code

G97.32

ICD-10 code description

Intraoperative hemorrhage and hematoma of a nervous system organ or structure complicating other procedure

Primary outcomes

1

Description

Bleeding

Timepoint

Record the amount of bleeding at the beginning of the surgery, at the end of the surgery and then every six hours for three days after the surgery

Method of measurement

Observing the amount of blood in surgical suction, gas and surgical lunggas, and blood observed in the surgical drain

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: 30 minutes before surgery, this group will be given an oral clonidine tablet of 0.2 mg to drink with 50 ml of water. This pill will be given to the patient only once; The drug used will be purchased from Abidi Pharmaceuticals.

Category

Prevention

2

Description

Intervention group 2: This group will be given the drug tranexamic acid 10 mg per kilogram and after the start of the surgery in the form of infusion. This medicine will be prepared as an infusion (20 mg in a 50 ml syringe), the infusion rate will be 10 ml per hour. The drug used will be purchased from Abidi Pharmaceuticals.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Loghman Hakim hospital

Full name of responsible person

Parisa Sezari

Street address

Loghman Hakim hospital, Makhsus St., South Kargar Ave., Tehran

City

Tehran

Province

Tehran

Postal code

13333631151

Phone

+98 21 5542 4040

Email

parissasezari@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Afshin Zarghi

Street address

7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

19839-63113

Phone

+98 21 23871

Email

info@sbmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor

organization/entity?

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Parisa Sezari

Position

Assistant profressor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Loghman Hakim hospital, Makhsus St., South Kargar Ave., Tehran

City

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Province

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Postal code

1333631151

Phone

+98 21 5542 4040

Email

parissasezari@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Parisa Sezari

Position

Assistant profressor

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Other areas of specialty/work

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Phone

+98 21 5542 4040

Email

parissasezari@yahoo.com

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Parisa Sezari

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Loghman Hakim hospital, Makhsus St., South Kargar Ave., Tehran

City

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Province

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1333631151

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Email

parissasezari@yahoo.com

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

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 is potentially shareable after de-identifying individuals.

When the data will become available and for how long

The access period will start 6 months after the results are published.

To whom data/document is available

Our data will only be available to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

Our data can be used if we have permission from our university and also if it is used for scientific purposes.

From where data/document is obtainable

To get this data, you should contact the senior researcher of this study.

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

The request must be made in writing to the research vice-chancellor of our university; Usually, a process of three to six months is required to review this request and if there is no ethical problem, this request is approved.

Comments