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)

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+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
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Loghman Hakim hospital, Makhsus St., South Kargar Ave., Tehran
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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
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19839-63113
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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
Assisstant profrssor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
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Person responsible for updating data

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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
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