Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Jul 2026

Comparison the effect of oral Clonidine and Tranexamic acid before Surgery on blood loss in lumbar spine surgery

Protocol summary

Study aim

The aim of study is to determine and compare the volume of bleeding and the hemodynamic parameters(Systolic and Diastolic Blood Pressure, Mean Arterial Pressure, Heart rate)during Lumbar Spine Surgery in three groups of Placebo, Tranexamic acid and Clonidine

Design

The clinical trial is randomized, with controlled group, with parallel triple blind groups

Settings and conduct

Participants of elective neurosurgical patients are selected after evaluating entry and exit criteria and are randomly assigned to receive Placebo, Tranexamic acid and Clonidine. Hemodynamic indices are recorded at the basic time(2hours before surgery), before anesthesia induction, 1,3,5,10,15 min after anesthesia, every 15 min during surgery, in the time of patient enter to the recovery and the volume of blood loss recorded in the end of the surgery

Participants/Inclusion and exclusion criteria

Age between 20 – 65 year;patients who consent to the informed consent to participate;ASA 1,2;do not use Beta blocker and Calcium blocker;do not use of sedative drugs;do not use of Opioids;do not addiction to Alcohol;not allergic reaction to drug;not allergic reaction to Local anesthetic drugs;not history of lumbar surgery;not risk factor of thrombosis;not use of anticoagulants drugs;not use of Digoxin;not use of Aspirin

Intervention groups

The first group received 600mg oral Tranexamic acid and one placebo tablet, the second group receive 0/2 mg tablet of Clonidine and 2 Capsules of placebo and the third group receive one tablet of Placebo and 2 Capsules of placebo 2 hours before surgery. All of the patients anesthetized with Midazolam, Fentanyl, Propofol, lidocaine and Cysatracurium, for maintenance of anesthesia we used Propofol and for controlled hypotension Remifentanil with goal of MAP between 80-85 mmHg

Main outcome variables

Systolic Blood Pressure;Diastolic Blood Pressure;Mean Arterial Pressure;Heart rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110528006617N4**
Registration date: **2020-07-11, 1399/04/21**
Registration timing: **retrospective**

Last update: **2020-07-11, 1399/04/21**
Update count: **0**

Registration date

2020-07-11, 1399/04/21

Registrant information

Name
Mehrdad Masoudifar
Name of organization / entity
Esfahan University of medical sciences
Country
Iran (Islamic Republic of)
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masoudifar@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2020-03-19, 1398/12/29

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison the effect of oral Clonidine and Tranexamic acid before Surgery on blood loss in lumbar spine surgery

Public title
The effect of oral Clonidine and Tranexamic on blood loss during surgery
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 20 – 65 year patients who consent to the informed consent to participate in the study ASA class 1 ,2
Exclusion criteria:
Beta blocker and Calcium blocker usage sedative drugs usage Opioids usage addiction to Alcohol allergic reaction to drugs allergic reaction to Local anesthetic drugs history of lumbar surgery risk factor of thrombosis anticoagulants drugs usage Digoxin usage Aspirin uage
Age
From **20 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
First with attention to the number of groups(3 groups)and the number of persons in every group, explained an amount of six block. So all of the situations that six person can stay on that block and stay on the study in form of couple in one of the triple group. After that randomized selection of the block with table of accidental numbers in fifteen times between all of the form in arrangement have done and fifteen blocks an amount of six selected, that allocated to every group two persons.
Blinding (investigator's opinion)
Triple blinded
Blinding description
We produced Placebo Capsule similar to Tranexamic Acid and Placebo tablets similar to Clonidine. The Tranexamic Acid group received 2 Capsules of Tranexamic Acid and one tablet of Placebo 2 hours before surgery, the Clonidine group received 2 Capsules of Placebo and one tablett of Clonidine 2 hours before surgery, the Placebo group received 2 Capsules of Placebo and one tablett of Placebo 2 hours before surgery. So the patients do not have any information about the intervention and the person who registered the information do not know which patient in which group ist and the study has three blind side.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical sciences
Street address
Isfahan University Of Medical Science, Hezar Jarib Ave
City
Isfahan
Province
Isfehan
Postal code
7346181746
Approval date
2020-06-22, 1399/04/02
Ethics committee reference number
IR.MUI.MED.REC.1399.244

Health conditions studied

1

Description of health condition studied
General anesthesia
ICD-10 code
M51.06
ICD-10 code description
Intervertebral disc disorders with myelopathy, lumbar region

Primary outcomes

1

Description
Systolic Blood Pressure
Timepoint
Basic time(two hours before surgery), before anesthesia induction, 1,3,5,10,15 min after anesthesia, every 15 min during surgery, in the time of patient enter to the

recovery

Method of measurement

mmHg , SAADAT Sphygmomanometer monitoring

2

Description

Diastolic Blood Pressure

Timepoint

Basic time(two hours before surgery), before anesthesia induction, 1,3,5,10,15 min after anesthesia, every 15 min during surgery, in the time of patient enter to the recovery

Method of measurement

mmHg , SAADAT Sphygmomanometer monitoring

3

Description

Mean Artherial Pressure

Timepoint

Basic time(two hours before surgery), before anesthesia induction, 1,3,5,10,15 min after anesthesia, every 15 min during surgery, in the time of patient enter to the recovery

Method of measurement

mmHg , SAADAT Sphygmomanometer monitoring

4

Description

Heart rate

Timepoint

Basic time(two hours before surgery), before anesthesia induction, 1,3,5,10,15 min after anesthesia, every 15 min during surgery, in the time of patient enter to the recovery

Method of measurement

beat/min , SAADAT ECG monitoring

5

Description

Volume Of Blood Loss

Timepoint

enter to the recovery, export from recovery

Method of measurement

Milliliter,volume of blood in the suction, Bloody gas

6

Description

Surgeon Satisfaction

Timepoint

End of the surgery

Method of measurement

Likert Scale

Secondary outcomes

1

Description

Hypotension

Timepoint

Basic time(two hours before surgery), before anesthesia induction, 1,3,5,10,15 min after anesthesia, every 15 min during surgery, in the time of patient enter to the recovery

Method of measurement

mmHg, SAADAT Sphygmomanometer monitor

2

Description

Hypertension

Timepoint

Basic time(two hours before surgery), before anesthesia induction, 1,3,5,10,15 min after anesthesia, every 15 min during surgery, in the time of patient enter to the recovery

Method of measurement

mmHg, SAADAT Sphygmomanometer monitor

3

Description

Tachycardia

Timepoint

Basic time(two hours before surgery), before anesthesia induction, 1,3,5,10,15 min after anesthesia, every 15 min during surgery, in the time of patient enter to the recovery

Method of measurement

beat/min ,SAADAT ECG monitoring

4

Description

Bradycardia

Timepoint

Basic time(two hours before surgery), before anesthesia induction, 1,3,5,10,15 min after anesthesia, every 15 min during surgery, in the time of patient enter to the recovery

Method of measurement

beat/min ,SAADAT ECG monitoring

Intervention groups

1

Description

Intervention group: The first intervention group(Tranexamic acid) receive 600mg oral Tranexamic acid and one placebo tablet 2 hour before surgery. Induction of anesthesia with 0/05mg/kg Midazolam, 3 microgram/Kg Fentanil, 2 mg/kg Propofol, 2mg/kg Lidocaine,Cisatracuriom 0/15 mg/kg and maintenance of anesthesia during the surgery is with 100microgram/kg/min Propofol and for induced of controlled hypotension infusion of 0/1-1 microgram/kg/min by goal of MAP(80-85mmHg)

Category

Treatment - Drugs

2

Description
Intervention group: The second intervention group(Clonidine) receive 0/2 mg tablet of Clonidine and 2 Capsules of placebo 2 hours before surgery. Induction of anesthesia with 0/05mg/kg Midazolam, 3 microgram/Kg Fentanil, 2 mg/kg Propofol, 2mg/kg Lidocaine,Cisatracuriom 0/15 mg/kg and maintenance of anesthesia during the surgery is with 100microgram/kg/min Propofol and for induced of controlled hypotension infusion of 0/1-1 microgram/kg/min by goal of MAP(80-85mmHg)

Category
Treatment - Drugs

3

Description
Control group: The second intervention group(Placebo) receive one tablet of Placebo and 2 Capsules of placebo 2 hours before surgery. Induction of anesthesia with 0/05mg/kg Midazolam, 3 microgram/Kg Fentanil, 2 mg/kg Propofol, 2mg/kg Lidocaine,Cisatracuriom 0/15 mg/kg and maintenance of anesthesia during the surgery is with 100microgram/kg/min Propofol and for induced of controlled hypotension infusion of 0/1-1 microgram/kg/min by goal of MAP(80-85mmHg)

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Alzahra hospital

Full name of responsible person
Mehrdad Masoudifar

Street address
Alzahra hospital, Sofe Blvd, Shahid Keshvari Highway

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alzahra@mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences

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
Esfahan 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
Esfahan University of Medical Sciences

Full name of responsible person
Mehrdad Masoudifar

Position
Associate Professor

Latest degree
Subspecialist

Other areas of specialty/work
Anesthesiology

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Person responsible for scientific inquiries

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Position
Associate Professor

Latest degree
Subspecialist

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

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

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

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