Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effect of two different doses of Labetalol on the rate of bleeding in lumbar spine fusion surgeries

Protocol summary

Study aim
The effect of Labetalol on the rate of lumbar vertebral fusion surgery bleeding

Design
A clinical trial with 2 parallel, double-blind, randomized, phase 3-2 groups is performed on 64 patients for lottery randomization.

Settings and conduct
This is a two-blind clinical trial that will be performed on 64 patients who are candidates for lumbar spine fusion surgery in Al-Zahra Hospital in Isfahan. One of the two groups is intervened, then the patients enter the groups one by one from the second patient onwards to complete the desired number in each group. In each group, after induction of anesthesia, the desired intervention is applied and the patient's vital signs and the amount of bleeding during the operation are measured and recorded. Clinical care is different from the person who injects the drug and is unaware of the type of intervention applied. The surgeon and the patient are also unaware of the intervention and are therefore blind.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age 18 to 50 years, candidate for lumbar spine fusion surgery, ASA anesthesia class I and II
Exclusion criteria: history of Labetalol allergy, history of heart block, history of respiratory disease such as asthma

Intervention groups
Intervention group A: After anesthesia, patients in this group receive Labetalol at a dose of 0.25 mg per kg body weight for 10 seconds, and then 2 mg / min as an infusion. Intervention group B: After anesthesia, patients in this group receive Labetalol at a dose of 0.25 mg per kg body weight for 10 seconds, and then 4 mg / min as an infusion.

Main outcome variables
The amount of bleeding during the operation

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160307026950N30**
Registration date: **2021-01-12, 1399/10/23**
Registration timing: **prospective**

Last update: **2021-01-12, 1399/10/23**
Update count: **0**

Registration date
2021-01-12, 1399/10/23

Registrant information

Name
Behzad Nazemroaya

Name of organization / entity
Isfahan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-01-20, 1399/11/01

Expected recruitment end date
2021-09-23, 1400/07/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of two different doses of Labetalol on the rate of bleeding in lumbar spine fusion surgeries

Public title
The effect of Labetalol on bleeding during lumbar spine fusion surgery
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Patients 18 to 50 years Candidate for lumbar spine fusion surgery ASA Class I and II Anesthesia
Exclusion criteria:
History of any allergy to Labetalol History of heart block History of lung diseases such as asthma
Age
From **18 years** old to **50 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **64**
Randomization (investigator's opinion)
Randomized
Randomization description
In this trial, there are two intervention groups, A and B, and randomization is done by assigning even and odd; In this way, patients are numbered according to their arrival time, then individual numbers enter group A and even numbers enter group B, until their number reaches 32 people in each group. Therefore, there is no directional choice and patients enter groups completely randomly.
Blinding (investigator's opinion)
Double blinded
Blinding description
This is a double-blind study; As the clinical caregiver is different from the person injecting the drug and is unaware of the type of intervention, the surgeon and patients are also unaware of the type of intervention applied and are therefore blind.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Isfahan University of Medical Sciences Committe for Ethics in Biomedical Research
Street address
Hezar Jarib St
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2020-09-23, 1399/07/02
Ethics committee reference number
IR.MUI.MED.REC.1399.526

Health conditions studied

1

Description of health condition studied
Bleeding rate during lumbar spine fusion surgery
ICD-10 code
M45
ICD-10 code description
Ankylosing spondylitis

Primary outcomes

1

Description
The amount of bleeding during the operation
Timepoint
After surgical incision until the end of the operation
Method of measurement
Counting the number of blood gases and measuring the amount of sucked blood

Secondary outcomes

1

Description
Heart Rate
Timepoint
Before surgery, during anesthesia, after anesthesia until the end of the operation, from the beginning of recovery to exit it
Method of measurement
ECG monitoring

2

Description
Blood Pressure

Timepoint
Preoperative time, anesthesia time, every 10 minutes from the start of the operation until the end of the recovery
Method of measurement
Barometer

3

Description
Percentage of arterial blood oxygen saturation
Timepoint
Before surgery, during anesthesia, after anesthesia until the end of the operation, from the beginning of recovery to exit it
Method of measurement
Pulse Oximeter

Intervention groups

1

Description
Intervention group A: After anesthesia, patients in this group receive Labetalol at a dose of 0.25 mg per kg body weight for 10 seconds, and then 2 mg / min as an infusion.
Category
Prevention

2

Description
Intervention group B: After anesthesia, patients in this group receive Labetalol in the amount of 0.25 mg per kg of body weight for 10 seconds, and then 4 mg / min as an infusion.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra hospital
Full name of responsible person
Behzad Nazemoroaya
Street address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Vice Chancellor for Research, Isfahan 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
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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