

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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

Country

Iran (Islamic Republic of)

Phone

+98 31 3212 3543

Email address

behzad_nazem@med.mui.ac.ir

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

Isfahan

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

Soffeh boulevard, Shahid Keshvari highway

City

Isfahan

Province

Isfahan

Postal code

8174675731

Phone

+98 31 3620 2020

Email

behzad_nazem@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo

Street address

Hezar Jarib

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3668 0048

Email

research@mui.ac.ir

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

Full name of responsible person

Heydar Almazy

Position

Medical student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

Hezar Jarib

City

Isfahan

Province

Isfahan

Postal code

8146713543

Phone
+98 31 3620 2020
Email
dr.haidara@hotmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Behzad Nazem roaya
Position
Professor assistant of Anesthesia and Intensive
carentensive care
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Hezar Jarib
City
Isfahan
Province
Isfahan
Postal code
8146713543
Phone
+98 31 3620 2020
Email
behzad_nazem@med.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Leyla Rafiei
Position

Nurse Anesthesia
Latest degree
Bachelor
Other areas of specialty/work
Anesthesiology
Street address
Hezar Jarib
City
Isfahan
Province
Isfahan
Postal code
8146713543
Phone
+98 31 3620 2020
Email
leylarafiei943@gmail.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

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