

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

Effect of premedication with oral clonidine on bleeding rate in lumbar laminectomy with pedicular screw

Protocol summary

(low, moderate, high)

Study aim

Effect of oral clonidine on bleeding rate in lumbar laminectomy

Design

100 patients that meet the inclusion criteria after surgery finished and the patient is discharged from anesthesia will be selected as research sample and then divided into intervention and control groups with binary blocking. The intervention group will receive clonidine and the control group will receive placebo. The study is a randomized, double-blind, placebo-controlled clinical trial.

Settings and conduct

Patients will be randomly divided into two groups according to the random number table. The intervention group received 0.5 mg clonidine and the control group received the same amount of placebo half an hour before surgery. Given that the study is double-blind. Both clonidine and placebo medications will be prepared each morning by the number of surgeries and number required by the plan's administrator. Envelope A contains oral clonidine and envelope B is a placebo. Each patient will receive the envelopes based on whether they are A or B coded by an anesthetist who is blinded of the type of drug. Intraoperative bleeding will then be assessed according to the amount of suction device filling and the surgeon's satisfaction with the operative field bleeding. In this study patient and anesthesiologist is blinded.

Participants/Inclusion and exclusion criteria

Entry requirements: All ASA I & II class patients aged 18-60 years
Exclusion criteria: Diabetic patients; Patients with systemic diseases (cardiovascular, pulmonary, liver and kidney,...); Use medicines interfering with clonidine

Intervention groups

The intervention group received 0.2 mg clonidine orally with water and control group receive placebo similar to first group half an hour before starting of surgery.

Main outcome variables

The effect of clonidine on intraoperative hemorrhage by evaluation of suction device filling and field operation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140107016117N4**

Registration date: **2020-01-06, 1398/10/16**

Registration timing: **registered_while_recruiting**

Last update: **2020-01-06, 1398/10/16**

Update count: **0**

Registration date

2020-01-06, 1398/10/16

Registrant information

Name

Bahman Naghipour Basmenj

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 3337 3950

Email address

naghipourb@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-22, 1398/10/01

Expected recruitment end date

2020-06-21, 1399/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of premedication with oral clonidine on bleeding rate in lumbar laminectomy with pedicular screw

Public title

Effect of oral clonidine on bleeding rate in lumbar laminectomy

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

All ASA I & II class patients aged 18-60 years

Exclusion criteria:

Patients with hypertension Diabetic patients Patients with systemic diseases(cardiovascular, pulmonary, liver and kidney,...) Use medicines Interfering with clonidine drugs such as Ibuprofen, Metalol, losartan, beta-blockers, diazepam and vitamin B1

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study we use balanced randomization that at first four blocks with 9 combination will be formed and blocks will be numbered from 1to9. Compared to the simple randomization method, in this method the size of equilibrium of intervention and placebo groups will be established both during and at the end of study(randomization method is pre and post accidental blocks and will be done by randlist software)

Blinding (investigator's opinion)

Double blinded

Blinding description

The anesthesiologist who has responsible for the patients management of anesthesia will administer the medicine(s) via coded syringes had been prepared previously and will not aware of the injected drug(clonidine or pelacebo), and anesthesia nurse who is responsible for collection of patients information and study variables and is unaware of the administered drug will record the check- list during surgery and in the recovery.Also the patient is unaware of the injected medicine.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tabriz University of Medical Sciences

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Faculty of Medicine, Golgasht Street

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East Azarbaijan

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5166614766

Approval date

2019-12-09, 1398/09/18

Ethics committee reference number

IR.TBZMED.REC.1398.936

Health conditions studied**1****Description of health condition studied**

Effect of clonidine on bleeding in lumbar laminectomy

ICD-10 code

M41.26

ICD-10 code description

Other idiopathic scoliosis, lumbar region

Primary outcomes**1****Description**

The rate of bleeding during surgery

Timepoint

During surgery

Method of measurement

Measurement of suctioned blood volume

Secondary outcomes**1****Description**

Duration of hospitalization

Timepoint

after surgery

Method of measurement

Examinations performed by the researcher

Intervention groups

1

Description

Intervention group: The patients of this group received 0.2 mg clonidine orally with water .

Category

Treatment - Drugs

2

Description

Control group:Control group: this group receive placebo similar to intervention group.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza hospital

Full name of responsible person

Bahman Naghipour

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr Abolghasem Joyban

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Vice chancellor for research, Daneshgah street, Tabriz

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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

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Bahman Naghipour

Position

Consultant

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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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 collected deidentified IPD, IPD collected for the primary outcome measure are to be shared

When the data will become available and for how long

Starting 6 months after publication

To whom data/document is available

Documents will be available for people working in academic institutions and also people working in businesses.

Under which criteria data/document could be used

There will be no specific limitations to the utilization of the data .

From where data/document is obtainable

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

Correspondence through email only

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

Tabriz University of Medical Sciences

Full name of responsible person

Bahman Naghipour

Position

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