Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jun 2026

Compare the effect of clonidine and tizanidine in controlling pain after lumbar fusion surgery

Protocol summary

Study aim
Comparison of the effect of clonidine and tetizanidine on pain control after lumbar fusion surgery

Design
Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 75 patients. Block permutated randomization was determined for randomization and also to hide the Concealment randomization process.

Settings and conduct
Patients undergoing lumbar fusion surgery referred to Imam Khomeini Medical Center in Sari were randomly selected by block method (Block permutated randomization). The intervention is not known. In order to hide the randomization process of Concealment, after randomization of patients, the drugs were placed in envelopes with specific numbers. The anesthesia nurse was given to the patients in the recovery who did not know the contents of the envelopes.

Participants/Inclusion and exclusion criteria
Patients undergoing lumbar fusion surgery referred to Imam Khomeini Medical Center in Sari 1- Confirmation of diagnosis by physical examination, CT scan MRI 2- The patient's desire to participate in the study and gain informed consent 3- Candidate for non-emergency lumbar fusion surgery 4 - Age between 70- 35 years No history of allergy to tizanidine and clonidine Absence of bradycardia (HR <60) in patients 7- No CNS disease (including epilepsy and seizures)

Intervention groups
Patients in the three groups, patients in group A, one 4 mg tizanidine tablet (manufactured by Galenus) orally and patients in group B, 4.0 mg clonidine (manufactured by company) Galen) and patients in group C will receive one placebo tablet orally one hour before surgery and 24 hours later.

Main outcome variables
Study of patients' pain intensity and drug use

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210904052371N1**
Registration date: **2021-10-19, 1400/07/27**
Registration timing: **retrospective**

Last update: **2021-10-19, 1400/07/27**
Update count: **0**

Registration date
2021-10-19, 1400/07/27

Registrant information

Name
Goli Aezi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 11 3311 9875

Email address
gaezi@mazums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-07-16, 1398/04/25

Expected recruitment end date
2019-10-22, 1398/07/30

Actual recruitment start date
2019-07-16, 1398/04/25

Actual recruitment end date
2019-10-12, 1398/07/20

Trial completion date
2019-10-22, 1398/07/30

Scientific title

Compare the effect of clonidine and tizanidine in controlling pain after lumbar fusion surgery

Public title
Compare the effect of clonidine and tizanidine in controlling pain after lumbar fusion surgery

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Confirm the diagnosis by physical examination, CT scan and MRI The patient's desire to participate in the study and gain informed consent Candidate for non-emergency lumbar fusion surgery Age between 70-35 years and No history of tizanidine allergy Absence of bradycardia (HR <60) in patients Absence of CNS disease No history of any previous back surgery

Exclusion criteria:
The patient's unwillingness to continue participating in the study at any time Taking narcotic painkillers 24 hours before the intervention Alcohol or drug abuse Occurrence of any unusual complication during surgery

Age
From **35 years** old to **70 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **75**
Actual sample size reached: **75**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients who met the inclusion criteria were determined using a computer program of random numbers by the method (Block permutated randomization) and also to hide the process of randomization Concealment after randomization of patients, drugs are placed in envelopes with specified numbers. These envelopes were given to patients at the time of administration by the anesthesia nurse in a recovery that did not know the contents of the envelopes. As a result, patients were randomly divided into three groups of 25 people A, B and C. Adequate explanations and training will be provided on how to determine the severity of pain, nausea, vomiting and itching after surgery using the VAS (Visual Analog Scale) criterion and how to use the PCA pump. According to the patients in the three groups, patients in group A received one 4 mg tizanidine tablet (manufactured by Galenus) orally and patients in group B received a 4.4 mg tablet. Gram clonidine (manufactured by Galenus) will be taken orally one hour before the operation and 24 hours later they will take one of these pills and patients in group C will be given one tablet in the same place as the placebo.

Blinding (investigator's opinion)
Double blinded

Blinding description
This study is double-blind and neither the patient nor the nurse of the project knows the type of intervention. Concealment randomization process After randomization of patients, the drugs were placed in envelopes with specific numbers, which were given to the patients when they were prescribed by the anesthesia nurse in the recovery, who did not know the contents of the envelopes.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
ﻩEthics Committee of Mazandaran University of Medical Sciences

Street address
Emam Khomeini hospital, Amir Mazandarani Ave

City
Sari

Province
Mazandaran

Postal code
48166-33131

Approval date
2019-07-16, 1398/04/25

Ethics committee reference number
IR.MAZUMS.IMAMHOSPITAL.REC.1398.082

Health conditions studied

1

Description of health condition studied
Pain control after cesarean section

ICD-10 code
G89.18

ICD-10 code description
Other acute postprocedural pain

Primary outcomes

1

Description
Intensity of patients' pain

Timepoint
48 hours

Method of measurement

Visual Analogue Scale

2

Description
The amount of drugs used
Timepoint
48 hours
Method of measurement
Visual Analogue Scale

Secondary outcomes

1

Description
The rate of nausea
Timepoint
48 hours
Method of measurement
Visual Analogue Scale

2

Description
The rate of vomiting
Timepoint
48 hours
Method of measurement
Visual Analogue Scale

3

Description
Itching rate
Timepoint
48 hours
Method of measurement
Visual Analogue Scale

4

Description
Dry mouth
Timepoint
48 hours
Method of measurement
Visual Analogue Scale

5

Description
Bradycardia rate
Timepoint
48 hours
Method of measurement
Visual Analogue Scale

6

Description
Headache rate
Timepoint
48 hours
Method of measurement
Visual Analogue Scale

7

Description
Vertigo
Timepoint
48 hours
Method of measurement
Visual Analogue Scale

8

Description
The rate of drowsiness
Timepoint
48 hours
Method of measurement
Visual Analogue Scale

Intervention groups

1

Description
Intervention group: Clonidine
Category
Rehabilitation

2

Description
Intervention group: tizanidine
Category
Rehabilitation

3

Description
Control group: Plasbo
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital, Sari
Full name of responsible person
Ali Mirani
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Majid Saedi
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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
Mazandaran 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
Mazandaran University of Medical Sciences
Full name of responsible person
Goli Azzi
Position
Associate professor
Latest degree
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Other areas of specialty/work
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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