Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Effect of Ultra-Low Dose interatechal Naloxone on pain intensity after lumbar laminectomy with fusion

Protocol summary

Study aim

Effect of Ultra-Low Dose interatechal Naloxone on pain intensity after lumbar laminectomy with fusion Special purposes: 1- Determining the severity of pain among the two groups. 2- Determine the pain intensity of patients at defined intervals after the beginning of the study in the two groups. 3- Determination of drug intake in two groups. 4- Determination of nausea, vomiting and itching in the two groups. 5- Comparison of pain intensity, nausea, vomiting and itching and urinary retention of patients in the two groups.

Design

This study is a randomized, double blind clinical trial

Settings and conduct

The aim of this study was to determine the effect of ultra-low dose naloxone on the severity of postoperative pain in patients undergoing laminectomy with elective lumbar fusion, referring to the center Educational treatment of Imam Khomeini (RA) Sari. Then, patients who have been admitted to study were randomly allocated (randomization) to two groups of intervention and control. The blindness of the study is that the drug was already prepared by an anesthetist nurse based on the Randomise table and the patient group and Then delivered to the surgeon And he injected medicine into the interactal space. In addition, the surgeon did not interfere with filling in the questionnaire form. Obviously, the anesthetist and the residents who filled in the relevant patient questionnaire had no information about the type of prescription drug to the patient

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1-Confirmation of diagnosis by physical examination and MRI 2-The patient's interest to participate in the study and obtain informed consent 3-Candidate for laminectomy with non-emergency lumbar fusion exclusion criteria: 1-The patient's unwillingness to continue studying at any time 2-Laminectomy with Emergency Lumbar Fusion 3-History of seizure 4- misuse of alcohol or drugs 5-The occurrence of any abnormal complications during surgery 6- No neurologic lesion 7-Proven diabetes 8- History of laminectomy surgery

Intervention groups

Patients were divided into two intervention and control groups.After completing laminectomy and releasing spinal cord and neural roots, the intervention group received 20 micrograms of naloxone produced by the pharmaceutical company (Toliddaro) and 0.2 mg of morphine, and for the control group only 0.2 mg of morphine with insulin syringe was injected by the surgeon to the intrathecal space.

Main outcome variables

intensity of pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110614006803N11**
Registration date: **2018-03-17, 1396/12/26**
Registration timing: **retrospective**

Last update: **2018-03-17, 1396/12/26**
Update count: **0**

Registration date

2018-03-17, 1396/12/26

Registrant information

Name
Abolfazl Firouzian
Name of organization / entity
Mazandaran University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 15 1222 6655
Email address
a.firouzian@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2015-08-23, 1394/06/01

Expected recruitment end date
2016-08-21, 1395/05/31

Actual recruitment start date
2015-08-23, 1394/06/01

Actual recruitment end date
2016-08-21, 1395/05/31

Trial completion date
empty

Scientific title
Effect of Ultra-Low Dose interatechal Naloxone on pain intensity after lumbar laminectomy with fusion

Public title
The effect of naloxone spinal injection on the severity of pain after spinal surgery

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Confirmation of diagnosis by physical examination and MRI The patient's interest to participate in the study and obtain informed consent Candidate for laminectomy with non-emergency lumbar fusion

Exclusion criteria:
The patient's unwillingness to continue studying at any time Laminectomy with Emergency Lumbar Fusion History of seizure Misuse of alcohol or drugs The occurrence of any abnormal complications during surgery No neurologic lesion Proven diabetes History of laminectomy surgery

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

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **80**
More than 1 sample in each individual
Number of samples in each individual: **5**
After entering the patients to the recovery, 1, 3, 6, 12, and 24 hours after surgery, the severity of pain (in addition to the mentioned hours) was evaluated and recorded exactly after sitting and walking.
Actual sample size reached: **77**
More than 1 sample in each individual
Actual sample size in each individual: **5**
After entering the patients to the recovery, 1, 3, 6, 12, and 24 hours after surgery, the severity of pain (in addition to the mentioned hours) was evaluated and recorded exactly after sitting and walking.

Randomization (investigator's opinion)
Randomized

Randomization description
Patients who have been admitted to the study were divided into two intervention and control groups using random allocation method (randomisation block).

Blinding (investigator's opinion)
Double blinded

Blinding description
The blindness of the study is that the drug was already prepared by an anesthetist nurse based on the Randomise table and the patient group and Then delivered to the surgeon And he injected medicine into the interactal space. In addition, the surgeon did not interfere with filling in the questionnaire form. Obviously, the anesthetist and the residents who filled in the relevant patient questionnaire had no information about the type of prescription drug to the patient.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

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

Street address
Deputy of Research and Technology of Mazandaran University of Medical Sciences, Moallem Square, Moallem Ave, Sari, Mazandaran, Iran.

City
sari

Province
Mazandaran

Postal code
4817844718

Approval date
2015-05-21, 1394/02/31

Ethics committee reference number
IR.MAZUMS.REC.1394.1899

Health conditions studied

1

Description of health condition studied
Pain after lumbar disc surgery

ICD-10 code
Y45.0

ICD-10 code description
Complications of medical and surgical care,Opioids and related analgesics

Primary outcomes

1

Description
Pain intensity after surgery
Timepoint
1, 3, 6, 12 and 24 hours after surgery
Method of measurement
Visual Analog Scale and Record in Questionnaire

2

Description
Amount of opioid consumption after surgery
Timepoint
1, 3, 6, 12 and 24 hours after surgery
Method of measurement
Visual Analog Scale and Record in Questionnaire

Secondary outcomes

1

Description
Pruritis after surgery
Timepoint
1, 3, 6, 12 and 24 hours after surgery
Method of measurement
Visual Analog Scale and Record in Questionnaire

2

Description
Vomiting and nausea after surgery
Timepoint
1, 3, 6, 12 and 24 hours after surgery
Method of measurement
Visual Analog Scale and Record in Questionnaire

Intervention groups

1

Description
Intervention group: After completing laminectomy and releasing spinal cord and neural roots, the intervention group received 20 micrograms of naloxone produced by the pharmaceutical company, and 0.2 mg of morphine with insulin syringe was injected by the surgeon to the interathecal space.
Category
Treatment - Drugs

2

Description
Control group: After surgery, only 0.2 mg of morphine with insulin syringe was injected to the intrathecal space by the surgeon.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Khomeini Hospital
Full name of responsible person
Abolfazl Firouzian MD, Assistant Professor
Street address
Emam Khomeini Hospital, Amir mazandarani Ave, Sari, Mazandaran, Iran.
City
sari
Province
Mazandaran
Postal code
4763853446
Email
a.firouzian@mazums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Majid Saeidi
Street address
Moallem square, Moallem street, Sari, Mazandaran, Iran.
City
Sari
Province
Mazandaran
Postal code
4814839953
Phone
+98 11 3334 7837
Email
research8876@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Sari 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
Abolfazl Firouzian

Position
Anesthesiologist, Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

Street address
Emam Khomeini Hospital, Amir mazandarani Ave, Sari, Iran

City
sari

Province
Mazandaran

Postal code
4814839953

Phone
+98 11 3334 7837

Email
A.firouzian@mazums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mazandaran University of Medical Sciences

Full name of responsible person
Abolfazl Firouzian MD

Position
Anesthesiologist, Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

Street address
Emam Khomeini Hospital, Amir Mazandarani Ave.

City
Sari

Province
Mazandaran

Postal code
4814839953

Phone
+98 11 3334 7837

Email
A.firouzian@mazums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Mazandaran University of Medical Sciences

Full name of responsible person
Fatemeh Younesi Rostami

Position
Resident of Anesthesiology

Latest degree
Medical doctor

Other areas of specialty/work
Anesthesiology

Street address
Emam Khomeini Hospital, Amir Mazandarani Ave, Sari, Mazandaran, Iran.

City
Sari

Province
Mazandaran

Postal code
4818845361

Phone
+98 11 3334 7837

Email
researching1905@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
there is no more information.

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable