# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Jun 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**

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**Phone**

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**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
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Emam Khomeini Hospital, Amir mazandarani Ave, Sari, Mazandaran, Iran.
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## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Mazandaran University of Medical Sciences
**Full name of responsible person**
Majid Saeidi
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Moallem square, Moallem street, Sari, Mazandaran, Iran.
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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**
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

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## Person responsible for updating data

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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