

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Sep 2026

### Effect of ultra low-dose naloxone on pain after lumbar disc surgery.

#### Protocol summary

##### Summary

The aim of this randomized double-blind trial is to evaluate effect of ultra low dose Naloxan on pain intensity after lumbar disc surgery. A total of 70 patients meeting eligibility criteria were randomly allocated into two equal groups. After establishment of monitoring the operating room, all patients with an identical anesthetic technique including midazolam 0.1mg/kg and Fentanyl 2mcg/kg for Pre-medication and Thiopental 5mg/kg and atracurium 0.5mg/kg for induction of anesthesia and during anesthesia N2O 50% and Isofluran 1MAC and morphine 0.1mg/kg and 0.1mg/kg atracurium based on the patient's needs will be put under general anesthesia. After emergence from anesthesia and log in recovery room for all patients for pain control PCA Pump will be used that contents 40mgr Morphine in 80cc Normal Saline with background infusion rate 2cc/hr and bolus dose 0.5cc and lockout 15min. For intervention group Naloxone 0.25mcg/kg/hr in 500cc normal saline will be infused Intravenously in 24 hours. For control group 500cc normal saline as a Placebo will be infused in 24 hours. severity of pain and nausea / vomiting and pruritus in both groups 1, 6, 12 and 24 hours after surgery will be recorded

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201312126803N5**  
Registration date: **2014-03-03, 1392/12/12**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2014-03-03, 1392/12/12

##### 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

Research Council of Mazandaran University of Medical Sciences Sari Mazandaran Iran 866-48175  
00981513261245 00981513262679  
medjournal@mazums.ac.ir www.mazums.ac.ir

##### Expected recruitment start date

2013-09-11, 1392/06/20

##### Expected recruitment end date

2014-05-10, 1393/02/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of ultra low-dose naloxone on pain after lumbar disc surgery.

##### Public title

The effect of naloxone on pain after surgery

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: 1) confirm the diagnosis with a physical examination and MRI 2) the willingness of patients to participate in the study and informed consent 3) non-emergency elective surgery discectomy 4) Age between 35-55 years Exclusion criteria: 1) patient reluctance

every time that continued in the study, 2) a history of psychological illness, 3) a history of seizures, 4) abuse of alcohol or drugs 5) any unusual complications during surgery, 6) lack of neurologic injury

#### Age

From **35 years** old to **55 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

No information

#### Sample size

Target sample size: **70**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

#### Placebo

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

Mazandaran University of Medical Sciences, Moallem Square. Sari Mazandaran Iran, Islamic Republic Of 4817844718

##### City

Sari

##### Postal code

4814839953

#### Approval date

2013-09-11, 1392/06/20

#### Ethics committee reference number

92-92

## 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, 6, 12 and 24 hours after surgery

#### Method of measurement

Visual Analog Scale and Record in Questionnaire

## Secondary outcomes

### 1

#### Description

Amount of opioid consumption after surgery

#### Timepoint

1, 6, 12 and 24 hours after surgery

#### Method of measurement

Visual Analog Scale and Record in Questionnaire

### 2

#### Description

Pruritis after surgery

#### Timepoint

1, 6, 12 and 24 hours after surgery

#### Method of measurement

Visual Analog Scale and Record in Questionnaire

### 3

#### Description

Vomiting and nausea after surgery

#### Timepoint

1, 6, 12 and 24 hours after surgery

#### Method of measurement

Visual Analog Scale and Record in Questionnaire

## Intervention groups

### 1

#### Description

Infusion of Naloxone 0.25mcg/kg/hr/IV in 500cc normal saline in 24 hours

#### Category

Treatment - Drugs

### 2

#### Description

Infusion of Normal saline 500cc/IV in 24 hours

#### Category

Placebo

## 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.

**City**

Sari

#### Sponsors / Funding sources

1

##### Sponsor

**Name of organization / entity**

Vice chancellor for research, Mazandaran University of Medical Sciences

**Full name of responsible person**

Ahmad Ali Enayati MD

**Street address**

Mazandaran University of Medical Sciences, Moallem Square.

**City**

Sari

**Grant name**

10506

**Grant code / Reference number**

92-92

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice chancellor for research, Mazandaran University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

empty

**Domestic or foreign origin**

empty

**Category of foreign source of funding**

empty

**Country of origin**

**Type of organization providing the funding**

empty

#### Person responsible for general inquiries

##### Contact

#### 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

**Other areas of specialty/work**

**Street address**

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#### Person responsible for updating data

##### Contact

**Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Behrouz Kheradmand MD

**Position**

Resident of anesthesiology

**Other areas of specialty/work**

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#### Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

empty

**Study Protocol**

empty

**Statistical Analysis Plan**

empty

**Informed Consent Form**

empty

**Clinical Study Report**

empty

**Analytic Code**

empty

**Data Dictionary**

empty