

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 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 surjury.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 025mcg/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

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Recruitment status

Recruitment complete

Funding source

Research Council of Mazandaran University of Medical Sciences Sari Mazandaran Iran 866-48175

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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

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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

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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.

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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

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Full name of responsible person

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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