

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Comparing the efficacy of different doses of pregabalin on postoperative pain in patients undergoing lumbar disc herniation surgery

Protocol summary

Summary

Objective: clinical trial of comparing the efficacy of different doses of pregabalin on postoperative pain in patients undergoing lumbar disc herniation surgery. Study design: randomization using random permuted blocks, convenience sampling, double-blind, single-center, phase II trial. Study population: all patients of lumbar disc herniation surgery with ASA PS I and II. Main inclusion criteria: age limitation 20-60 years; candidates of lumbar disc herniation surgery with ASA PS I and II. Main exclusion criteria: renal and liver dysfunction; usage of alcohol or any other drug; internal disease such as uncontrolled diabetes or hypertension; NSAID usage 24 hours prior to surgery; emergent surgery for any reason. Sample size: 90. Interventions: First group: administration of placebo as oral capsules containing starch an hour before surgery; second group: administration of pregabalin (Lyrica) orally 75 mg one hour prior to surgery; third group: administration of pregabalin (Lyrica) orally 150 mg one hour prior to surgery. Intervention time: before the operation. Outcomes: postoperative pain.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017030132832N1**
Registration date: **2017-05-24, 1396/03/03**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-05-24, 1396/03/03

Registrant information

Name

Fatemeh Dalaki

Name of organization / entity

Zahedan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Zahedan University of Medical Sciences

Expected recruitment start date

2016-06-04, 1395/03/15

Expected recruitment end date

2017-06-05, 1396/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the efficacy of different doses of pregabalin on postoperative pain in patients undergoing lumbar disc herniation surgery

Public title

Evaluation the effect of two different doses of pregabalin before surgery on postoperative pain after lumbar disc surgery

Purpose

Supportive

Inclusion/Exclusion criteria

Main inclusion criteria: age between 20-60 years old; candidates of lumbar disc herniation surgery with ASA PS I and II. Main exclusion criteria: renal and liver dysfunction; usage of alcohol or any other drug; internal

disease such as uncontrolled diabetes or hypertension; NSAID usage 24 hours prior to surgery; emergent surgery for any reason.

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **90**

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 Zahedan University of Medical Sciences

Street address

Ethics Committee of Zahedan University of Medical Sciences, Zahedan University of Medical Sciences, Dr.Hesabi Square, Zahedan

City

Zahedan

Postal code

Approval date

2016-04-20, 1395/02/01

Ethics committee reference number

IR.ZAUMS.REC.1395.16

Health conditions studied

1

Description of health condition studied

Lumbar disc herniation surgery

ICD-10 code

M51.9

ICD-10 code description

Other intervertebral disc disorders

Primary outcomes

1

Description

Postoperation pain

Timepoint

Two hours, four hours, eight hours, 12 hours and 24 hours after surgery

Method of measurement

VAS Criteria

Secondary outcomes

empty

Intervention groups

1

Description

First group(control): administration of placebo as oral capsules containing starch an hour before surgery

Category

Placebo

2

Description

Intervention group I: administration of pregabalin (Lyrica) orally 75 mg one hour prior to surgery

Category

Treatment - Drugs

3

Description

Intervention group II: administration of pregabalin (Lyrica) orally 150 mg one hour prior to surgery.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali-ebn Abi Taleb Hospital, Zahedan

Full name of responsible person

Fatemeh Dalaki

Street address

Operation room, Zahedan Ali-ebn Abi Talib Hospital, Salamat Blvd, Dr.Hesabi Sq., Zahedan

City

Zahedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Zahedan University of Medical Sciences

Full name of responsible person

Mohsen Taheri

Street address

Vice chancellor for research, Zahedan University of Medical Sciences, Zahedan

City

Zahedan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellor for research, Zahedan 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****Name of organization / entity**

Zahedan University of Medical Sciences

Full name of responsible person

Fatemeh Dalaki

Position

Anesthesiology Residence

Other areas of specialty/work**Street address**

Operation room, Ali-ebn Abi Taleb Hospital, Salamat Blvd, Dr.Hesabi Sq., Daneshgah Ave., Zahedan

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Zahedan University of Medical Sciences

Full name of responsible person

Dr. Shahram Borjian

Position

Associate Professor of General anaesthesia

Other areas of specialty/work**Street address**

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Zahedan University of Medical Sciences

Full name of responsible person

Fatemeh Dalaki

Position

Anesthesiology Residence

Other areas of specialty/work**Street address**

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Web page address**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