

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Evaluation of the efficacy and safety of oral pregabalin on post Lichtenstein herniorrhaphy pain relief in comparison with control group, Mousavi Hospital, Zanjan, 2014-2015

Protocol summary

Summary

Aim: Evaluation of the efficacy and safety of pregabalin in post herniorrhaphy surgery pain relief. Major inclusion criteria: male patient; unilateral hernia; elective surgery. Major exclusion criteria: emergency surgery; significant medical and drug history that may interfere with outcomes. Sample size and population: Sixty male patients with unilateral inguinal hernia who refer to Zanjan Ayatollah Mousavi hospital. Intervention and time: The patients are randomly allocated to two groups: The pregabalin group receive single-dose 300 mg oral pregabalin 2 h before and 150 mg pregabalin 12 and 24 h after surgery in addition to routine post operative medication, and the control group just receive routine medication. The operations are performed by the same surgeon with the same technique. Main outcomes: Postoperative pain that is evaluated during walking and lying with a visual analogue scale (VAS) 12 h, 24 h, 3 and 7 days after surgery. Pethidine consumption and the adverse effects of pregabalin are also evaluated.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2015041821817N1**
Registration date: **2015-07-11, 1394/04/20**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-07-11, 1394/04/20

Registrant information

Name

Vahid Salehi

Name of organization / entity

Zanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 24 3313 0001

Email address

zums90vhds@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Zanjan University of Medical Sciences

Expected recruitment start date

2014-10-02, 1393/07/10

Expected recruitment end date

2015-08-06, 1394/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the efficacy and safety of oral pregabalin on post Lichtenstein herniorrhaphy pain relief in comparison with control group, Mousavi Hospital, Zanjan, 2014-2015

Public title

The effect of oral Pregabalin on post herniorrhaphy pain relief

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Male patients over 18 years old;

unilateral inguinal hernia; elective surgery. Exclusion criteria: Emergency surgery; incarceration; simultaneous other operations; history of diabetes mellitus; peptic ulcer; gastritis; renal failure; neuropsychiatric disorders; opium abuse; neuropsychiatric medications; presenting drug adverse effects.

Age

From **18 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Zanjan University of Medical Sciences

Street address

Azadi street, Zanjan

City

Zanjan

Postal code**Approval date**

2014-10-02, 1393/07/10

Ethics committee reference number

ZUMS.REC.1392.117

Health conditions studied**1****Description of health condition studied**

Inguinal hernia

ICD-10 code

K40.9

ICD-10 code description

Unilateral or unspecified femoral hernia, without obstruction or gangrene

Primary outcomes**1****Description**

Pain

Timepoint

12 and 24h, 3 and 7 days after operation

Method of measurement

Visual Analogue Scale

2**Description**

Pethidine consumption

Timepoint

First 24 h post operation, total dosages during admission

Method of measurement

The number of dosages as patient request (according to his weight)

3**Description**

Oral analgesic (gellofen) consumption

Timepoint

Till 3 rd and till 7 th day post operation

Method of measurement

The count of capsules consumption

Secondary outcomes**1****Description**

Drug adverse effects

Timepoint

12 and 24 h post operation, 3 and 7 days post op

Method of measurement

Filling the data collecting form

Intervention groups**1****Description**

Intervention group: receive single-dose 300 mg oral pregabalin 2 h before and 150 mg pregabalin 12 and 24 h after surgery in addition to 1 mg per kg of pethidine PRN.

Category

Treatment - Drugs

2**Description**

Control group: just receive 1 mg per kg of pethidine PRN.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Mousavi Hospital

Full name of responsible person

Vahid Salehi

Street address

General surgery ward, Ayatollah Mousavi Hospital

City

Zanjan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Dr Mohammad Masoud Vakili

Street address

Vice chancellor for research, University of Medical Sciences, Azadi Blvd, Zanjan

City

Zanjan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Zanjan 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

Zanjan University of Medical Sciences

Full name of responsible person

Vahid Salehi

Position

General surgery resident

Other areas of specialty/work

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Dr Mohammad Hossein Moghimi, Dr Vahid Salehi

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Web page address

Person responsible for updating data

Contact

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Vahid Salehi

Position

General surgery resident

Other areas of specialty/work

Street address

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Fax

Email

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