Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jul 2026

Clinical trial comparing effect different doses of Pregabalin on postoperative pain in patients Laparoscopic Hysterectomy

Protocol summary

Summary

Postoperative pain control is a clinical challenge. Many methods have been proposed to reduce pain after surgery. Today, many pharmaceutical drugs such as pregabalin more common after surgery. The purpose of this study was to investigate the effect of different doses of pregabalin before and after laparoscopic hysterectomy to prevent pain from the surgery. The results of this study will be to determine the optimal dose. In this clinical blind randomized placebo-controlled study, 70 women 30 to 65 years, candidates for hysterectomy laparoscopic with ASA physical status I-II, without long analgesics consumption or experience chronic pelvic pain were selected and will be classified into one of 4 groups: placebo, group therapy 75 mg, 150 mg and 300 mg. For mentioned treatment groups, the night before, half an hour before the operation and also 6 hours after surgery, according to given category, pregabalin capsules 75, 150 and 300 mg and for the control group in the same way, the placebo will be administered. Then, the mean pain by visual analog scale, side effects, nausea and vomiting after surgery, narcotic dose (pethidine) and conscious level of patients under study, will be evaluated and recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201412028897N3**
Registration date: **2014-12-22, 1393/10/01**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-12-22, 1393/10/01

Registrant information

Name
Safoura Rouholamin
Name of organization / entity
Isfahan University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2014-11-22, 1393/09/01

Expected recruitment end date

2015-04-30, 1394/02/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial comparing effect different doses of Pregabalin on postoperative pain in patients Laparoscopic Hysterectomy

Public title

Pregabalin effect on pain after Laparoscopic Hysterectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with elective laparoscopic hysterectomy with ASA physical status I-II; without chronic pelvic pain and long-analgesics consumption.

Exclusion criteria: patients with history of the chronic pain or daily consumption of analgesics types; have uncontrolled underlying disease (diabetes, hypertension); renal or hepatic failure; suffering from mental illness; major depression or bi-polar; with a history of alcohol or drug abuse; sensitivity to study medication.

Age
From **30 years** old to **65 years** old

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Tehran University of Medical Sciences

Street address
Keshavarz Bul, Pourcina St

City
Tehran

Postal code
8184851153

Approval date
2014-11-21, 1393/08/30

Ethics committee reference number
27556-30-04-93

Health conditions studied

1

Description of health condition studied
Relation between Pragabalin using and post oprative pain after Laparascopic Hystrectomy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Post Oprative Pain

Timepoint
Assay of pain at 0, 2, 4, 6, 8, 12 and 24 hours after surgery

Method of measurement
Visual Analog Score (VAS) Form of pain

2

Description
Pethedine Consumption

Timepoint
First 24 hours after surgery

Method of measurement
Pethidin consumption doses

3

Description
Nausea and Vomiting

Timepoint
First 24 hours after surgery

Method of measurement
Antiemetic doses

4

Description
Sedation Score

Timepoint
First 24 hours after surgery

Method of measurement
Examination and observation of the patient

Secondary outcomes

1

Description
Time of Anaesthesia

Timepoint
From induction of anesthesia time to extubation

Method of measurement
Time observation

2

Description
Recovery Duration

Timepoint
From extubation to transfer to the ward

Method of measurement
Time observation

3

Description
Patient Satisfaction

Timepoint
First 24 hours after surgery
Method of measurement
Questionnarie

4

Description
Pregabalin Side Effects
Timepoint
First 24 hours after surgery
Method of measurement
Examination and observation of the patient

Intervention groups

1

Description
Administration of 75 mg pregabalin, night before and 30 min before and 6 hours after surgery
Category
Treatment - Drugs

2

Description
Administration of 150 mg pregabalin, night before and 30 min before and 6 hours after surgery
Category
Treatment - Drugs

3

Description
Administration of 300 mg pregabalin, night before and 30 min before and 6 hours after surgery
Category
Treatment - Drugs

4

Description
Administration of placebo, night before and 30 min before and 6 hours after surgery
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Arash Hospital, laparascopy ward
Full name of responsible person
Safoura Rouholamin
Street address
Arash Hospital, Rashid St, Tehranpars
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Vice chancllor of Tehran University of Medical Sciences
Street address
Keshavarz Bul, Pourcina St
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Isfahan University of Medical Sciences
Full name of responsible person
Safoura Rouholamin
Position
Assistant Professor
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Person responsible for scientific inquiries

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Tehran University of Medical Sciences
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Zahra Asgari

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Associated Professor

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Arash Hospital, Rashid Street, Tehranparse

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Web page address

Person responsible for updating data

Contact

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