

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

Effects of Gabapentin on postoperative pain after laparoscopic cholecystectomy

Protocol summary

Summary

In this study, 80 patients, aged 35-60, class I, II American Society of Anesthesiology, candidate for elective laparoscopic cholecystectomy, randomly divided into 2 equal 40 patients. Patients with a history of seizures and psychiatric disorders are excluded. The patients receive Gabapentin 600 mg in intervention group and capsule without Gabapentin, empty capsule, orally as a placebo in control group 1.5 hours before surgery. Anesthetic premedication included midazolam (0.01-0.03 mg/kg), fentanyl (3 µg/kg), morphine (0.1 mg/kg), dexamethasone (8 mg), metoclopramide (10 mg) and lidocaine (1 mg/kg). Anesthesia induced with Sodium thiopental (5 mg/kg) and atracurium (0.5 mg/kg). Anesthesia is maintained with Isoflurane 0.6-1.2% and N₂O 50% plus O₂ 50%. All patients receive intravenous meperidine (25 mg) after gallbladder removal. The patients are reversed with 2.5 mg Neostigmine and 1 mg Atropine. The Pain score evaluated with Visual Analog Scale (0-10) every 2 hours for 12 hours then every 6 hours for next 12 hours. If the pain scores greater than 4, Intravenous Morphine (3 mg) is administered. All patients evaluated for nausea and vomiting, vertigo and drowsiness for 24 hours. Finally, we compare Morphine consumption and patient's pain scores of two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201203107752N3**
Registration date: **2012-05-19, 1391/02/30**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-05-19, 1391/02/30

Registrant information

Name

Parviz Amri Maleh

Name of organization / entity

Babol University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor of research of Babol Medical Sciences

Expected recruitment start date

2012-02-28, 1390/12/09

Expected recruitment end date

2012-07-30, 1391/05/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Gabapentin on postoperative pain after laparoscopic cholecystectomy

Public title

Effects of Gabapentin on postoperative pain after laparoscopic cholecystectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Class I, II, American Society of Anesthesiology; 35-60 years; Elective Laparoscopic cholecystectomy. Exclusion criteria: History of epilepsy; Psychological disorder; History of anticonvulsant drug

usage; laparotomy during laparoscope surgery; surgery time longer than 3 hours; opioid addiction; Bleeding during surgery that needs blood transfusion.

Age

From **35 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

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

Vice-chancellor of research of Babol University of Medical Sciences

Street address

Gangafrooz St, Babol University of Medical Sciences

City

Babol

Postal code

4717641367

Approval date

2012-02-28, 1390/12/09

Ethics committee reference number

30/5895/23/پ/ج

Health conditions studied

1

Description of health condition studied

Cholecystectomy

ICD-10 code

Acquired a

ICD-10 code description

Z90.4

Primary outcomes

1

Description

Postoperative pain

Timepoint

72 hours postoperative

Method of measurement

Visual Analog Scale

2

Description

The amount of Morphine

Timepoint

72 hours postoperative

Method of measurement

miligram

Secondary outcomes

1

Description

Sedation

Timepoint

72 h postoperative

Method of measurement

Ramsay sedation scale

2

Description

Nausea and vomiting

Timepoint

72 h postoperative

Method of measurement

Yes/ No

3

Description

Vertigo

Timepoint

72 h postoperative

Method of measurement

Yes/ No

Intervention groups

1

Description

Intervention: Gabapentin 600 mg per oral 1.5 hours before surgery .

Category

Treatment - Drugs

2

Description

In control group : placebo (capsule without gabapentin)
1.5 hours before surgery

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shaid Beheshti Hospital

Full name of responsible person

Nikbakhsh, Novin

Street address

Gangafrooz St, Shahid Behshti Hospital

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor of research of Babol University of
Medical Sciences

Full name of responsible person

Mostafazadeh, Amrolah

Street address

Gangafrooz St, Babol University of Medical sciences

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Grant name

Grant code / Reference number

9032439

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

Yes

Title of funding source

Vice-chancellor of research of Babol 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

Babol University of Medical Sciences

Full name of responsible person

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Position

Anesthesiologist,FCCM

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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