Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 May 2026

Effects of Gabapentin on postoperative pain after laparoscopic cholecystectomy

Protocol summary

Summary

In thisl study,80 patients,aged 35-60 , class I, II America 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 (3µg/kg), morphine(0.1mg/kg), dexamethasone(8mg), metoclopramide(10 mg) and lidocaine (1mg/kg) I. Anesthesia induced with Sodium thiopental (5mg/kg) and atracurium (0.5mg/kg). Anesthesia is maintained with Isoflurane0.6-1.2% and N2O 50% plus O2 50%.All patients receive intravenous meperidine(25 mg) after gallbladder removal. The patients are reversed with 2.5mg Neostigmine and 1mg Atropine. The Pain score evaluate with Visual Analog Scale (0-10) every 2 hour for 12 hours then every 6 hour for next 12 hours. If the pain scores greater than 4, Intravenous Morphine(3 mg) is administrated. All patients evaluate 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
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Name of organization / entity
Babol University of Medical Sciences
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Iran (Islamic Republic of)
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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, America Society of Anesthesiology;35-60years; 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/ژ/پ

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 paine

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

Ganafrooz 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

Amrimaleh, Parviz

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Anestesiologist,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