

Effect of pregabalin in acute post-operative pain and functional recovery for laparoscopic cholecystectomy

Submission date	Recruitment status	<input type="checkbox"/> Prospectively registered
03/01/2007	No longer recruiting	<input type="checkbox"/> Protocol
Registration date	Overall study status	<input type="checkbox"/> Statistical analysis plan
13/02/2007	Completed	<input checked="" type="checkbox"/> Results
Last Edited	Condition category	<input type="checkbox"/> Individual participant data
26/03/2021	Surgery	

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

N/A

Study information

Scientific Title

Effect of pregabalin in acute post-operative pain and functional recovery for laparoscopic cholecystectomy

Study objectives

Pregabalin provides superior post-operative pain control, lower analgesic consumption and better recovery profile compared with placebo.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval received from the University Health Network Research Ethic Board, Toronto, Ontario, Canada, on the 15th December 2006 (ref: UHN REB 05-0745-B).

Study design

Double blind, randomised, controlled study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Postoperative pain during laparoscopic cholecystectomy

Interventions

During laparoscopic cholecystectomy depending on the randomised three groups patients will receive three doses of pregabalin 50 mg/75 mg, first dose one hour after surgery and then every twelve hours or oral placebo.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Pregabalin

Primary outcome(s)

1. Postoperative pain score (Numerical Rating Score [NRS]) in Post Anaesthesia Care Unit (PACU), one hour, six hours, day one, day two and day seven after surgery at rest and movement
2. Time to first analgesic consumption
3. Discharge time from PACU
4. Consumption of analgesics in the postoperative period up to day seven

Key secondary outcome(s)

1. General tolerability of the regimens
2. Sleep quality
3. Quality of Recovery 40-item questionnaire (QoR-40)

4. Adverse effects including Opioid-Related Symptom Distress Scale (ORSDS)

5. Patient satisfaction

Completion date

21/06/2008

Eligibility

Key inclusion criteria

1. Patients 18 to 65 years of age undergoing cholecystectomy under general anesthesia
2. Able to tolerate standard medications - 1000 mg of acetaminophen and 500 mg of naproxen

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

162

Key exclusion criteria

1. Clinically diagnosed acute pancreatitis requiring urgent cholecystectomy
2. Allergy to gabapentin or pregabalin
3. Allergy to Non-Steroidal Anti-Inflammatory Drugs (NSAID) or acetaminophen
4. No analgesic within 24 hours before surgery (other than premedication)
5. Patients with Body Mass Index (BMI) more than 40
6. Serious organ disease
7. Creatinine clearance less than or equal to 60 mL
8. Chronic pain patients requiring more than 30 mg morphine per day or equivalent
9. Severe psychiatric disease
10. Drug addiction
11. Pregnancy
12. Language barrier

Date of first enrolment

21/01/2007

Date of final enrolment

21/06/2008

Locations

Countries of recruitment

Canada

Study participating centre

McL 2-405
Toronto
Canada
M5T 2S8

Sponsor information

Organisation

Pfizer (Canada)

ROR

<https://ror.org/059g90c15>

Funder(s)

Funder type

University/education

Funder Name

Support from Department of Anesthesiology and Pain Management, University of Toronto (Canada)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/08/2010	26/03/2021	Yes	No