

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

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

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

## 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**

Intentional

**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?
<a href="#">Results article</a>		01/08/2010	26/03/2021	Yes	No