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

Submission date 03/01/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 13/02/2007	**Overall study status** Completed	
Last Edited 26/03/2021	**Condition category** Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

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 measure
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

Secondary outcome measures
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

Overall study start date
21/01/2007

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
135

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)

Sponsor details
17300 Trans-Canada Highway
Kirkland
Quebec
Canada
H9J 2M5

Sponsor type
Industry

Website
http://www.pfizer.ca

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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