

Analgesic drug combinations in post-operative movement-evoked pain

Submission date 21/04/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 30/05/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 27/01/2009	Condition category Surgery	<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

Protocol serial number
ANAE-099-03

Study information

Scientific Title

Study objectives

The central hypothesis of this application is that a combination of the COX-2I, meloxicam, and the 3-alkylated gamma-amino butyric acid (GABA) analog, gabapentin, will reduce evoked pain and opioid consumption to a greater degree than either drug alone. It is also postulated that superior reduction of evoked pain will result in enhancement of post-operative physiological recovery.

The central hypothesis will be tested and the objective of the trial accomplished by pursuing the following specific objective:

To evaluate the efficacy of reducing evoked post-operative pain, and improving post-operative pulmonary performance, by:

1. The COX-2 inhibitor non-steroidal anti-inflammatory drug (NSAID) meloxicam
2. The 3-alkylated gamma-amino butyric acid (GABA) analog gabapentin, or
3. A combination of meloxicam and gabapentin

Ethics approval required

Old ethics approval format

Ethics approval(s)

Queen's University Research Ethics Board approved in June 2004

Study design

Double-blind randomised parallel group trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Post-operative pain

Interventions

Enrolled patients will be randomised, in a double-blind fashion, to receive oral administration of one of three possible treatments (n = 32 patients per group):

1. Meloxicam 15 mg per day
2. Gabapentin 1200 to 1600 mg per day
3. A combination of meloxicam 15 mg per day and gabapentin 1200 to 1600 mg per day

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Gabapentin, meloxicam

Primary outcome(s)

Cough-evoked pain intensity

Key secondary outcome(s)

1. Pain intensity at rest, while sitting, and at peak expiration
2. Peak expiratory flow rate, forced vital capacity, forced expiratory volume over 1 second
3. Total analgesic consumption (fentanyl on day of surgery, morphine equivalents on postoperative days 1 and 2)
4. Side effects, blinding questionnaire responses
5. Time to discharge from hospital, time to return to work (in those working outside of the home)

Completion date

30/12/2006

Eligibility

Key inclusion criteria

1. Patients aged 18 or older (either sex) requiring elective laparoscopic cholecystectomy
2. American Society of Anesthesiologists class 1 or 2
3. Body mass index (weight in kilograms/[height in meters]²) less than or equal to 35

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Known history of hypersensitivity to any agents to be used in the study
2. History of serious organ disease/dysfunction
3. History of persistent pain (excluding gallbladder pain) prior to surgery
4. Daily intake, or intake within 48 hours prior to surgery, of any glucocorticoid agents, non-steroidal anti-inflammatory agents, or other analgesics, not including daily administration of less than or equal to 325 mg of aspirin for cardiovascular prophylaxis
5. History or evidence of substance or alcohol abuse
6. History of a major psychiatric disorder
7. History of a bleeding disorder
8. History of peptic ulcer disease
9. History of moderate to severe asthma with forced expiratory volume in 1 second (FEV1) less than 65% predicted
10. History of a seizure disorder requiring treatment with an anticonvulsant drug
11. A language barrier in communicating with research staff

Date of first enrolment

09/11/2004

Date of final enrolment

30/12/2006

Locations

Countries of recruitment

Canada

Study participating centre

Victory 2 Pavillion

Ontario

Canada

K7L 2V7

Sponsor information

Organisation

Physician's Services Incorporated (PSI) Foundation (Canada)

ROR

<https://ror.org/0385yzn06>

Funder(s)

Funder type

Charity

Funder Name

Physician's Services Incorporated (PSI) Foundation (Canada) (ref: 03-30)

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	results	01/02/2009		Yes	No