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Analgesic drug combinations in post-operative movement-evoked pain

Submission date	Recruitment status	[_] Prospectively registered
21/04/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/05/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
27/01/2009	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
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-inflamatory 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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

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 measure
Cough-evoked pain intensity

Secondary outcome measures
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)

Overall study start date
09/11/2004

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
96

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)

Sponsor details
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Sponsor type
Charity

Website
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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

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	results	01/02/2009		Yes	No