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Combination pharmacotherapy for post-surgical pain and functional recovery

Submission date 29/07/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 28/10/2009	**Overall study status** Completed	
Last Edited 19/05/2016	**Condition category** Signs and Symptoms	

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-152-09

Study information

Scientific Title
A double-blind randomised controlled trial of triple versus double non-opioid therapy for post-surgical pain and functional recovery

Acronym
EP-TRIPLE

Study objectives
A triple combination of non-opioid drugs (i.e. acetaminophen, meloxicam and gabapentin) will reduce post-surgical evoked pain to a greater degree than any of the three respective double-drug combinations (i.e. meloxicam, acetaminophen and gabapentin is superior to meloxicam and acetaminophen, meloxicam and gabapentin and acetaminophen and gabapentin).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Queen's University Research Ethics Board, 02/11/2009

Study design
Double-blind randomised controlled parallel-design four-arm trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Post-surgical pain following abdominal hysterectomy

Interventions
Enrolled patients will be randomised, in a double-blind fashion, to receive oral administration of one of four possible treatments:
1. Meloxicam 15 mg/day and acetaminophen 4000 mg/day and gabapentin 1800 mg/day

2. Meloxicam 15 mg/day and acetaminophen 4000 mg/day
3. Meloxicam 15 mg/day and gabapentin 1800 mg/day
4. Acetaminophen 4000 mg/day and gabapentin 1800 mg/day

Total duration of treatment is from one hour before surgery to 48 hours after surgery. Total duration of follow-up is 30 days following surgery for all trial arms.

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Meloxicam, acetaminophen, gabapentin

Primary outcome measure
Cough-evoked pain intensity, recorded on the day of surgery and post-operative days one and two.

Secondary outcome measures
1. Pain intensity at rest, during sitting, and with forced expiration
2. Retrospective measure of average nocturnal pain intensity from 10 pm (previous day) to 8 am (current morning) recorded at 8 am on post-operative days 1 and 2
3. Peak expiratory flow rate, forced vital capacity, forced expiratory volume over one second
4. Total opioid consumption (fentanyl on day of surgery, morphine [nurse-administered and patient-controlled] on day of surgery and post-operative days 1 and 2)
5. Time to fulfilment of post-anaesthetic care unit discharge criteria
6. Presence and severity (mild, moderate or severe) of 12 opioid-related symptoms (evaluated by open-ended questioning): nausea, vomiting, constipation, difficulty passing urine, difficulty concentrating, drowsiness or difficulty staying awake, feeling light-headed or dizzy, feeling confused, feelings of general fatigue or weakness, itchiness, dry mouth, and headache
7. Other side effects and their severity (mild, moderate or severe)
8. Time to bladder extubation; time to first urination after bladder catheter removal; time to first bowel movement
9. Timed 'up and go' test
10. Blinding questionnaires
11. Modified Brief Pain Inventory
12. Time to discharge from hospital, time to return to regular activities and return to work (in those working outside of the home)
13. 30-day post-operative surgical pain intensity (present rest pain, present cough pain and worst pain in past week)

Recorded on the day of surgery and post-operative days one and two. On post-operative day 30, only pain and major adverse events will be recorded.

Overall study start date
01/08/2009

Completion date
31/07/2012

Eligibility

Key inclusion criteria
1. Female patients aged 18 or older requiring elective abdominal hysterectomy
2. American Society of Anaesthesiologists class 1 or 2
3. Body mass index less than or equal to 35 kg/m^2

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
144

Key exclusion criteria
1. Hypersensitivity to any study drugs
2. Serious organ disease/dysfunction
3. Persistent pre-operative pain
4. Daily intake, or intake 48 hours pre-operatively, of any analgesic
5. Alcohol/substance abuse
6. A major psychiatric disorder
7. A bleeding disorder
8. Peptic ulcer disease
9. Asthma/chronic obstructive pulmonary disease (COPD)
10. A seizure disorder
11. Any language barrier to communicating with research staff
12. Aged over 80 years

Date of first enrolment
01/08/2009

Date of final enrolment
31/07/2012

Locations

Countries of recruitment
Canada

Study participating centre

Kingston General Hospital
Kingston
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Sponsor information

Organisation
Queen's University (Canada)

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Sponsor type
University/education

Website
http://www.queensu.ca/

ROR
https://ror.org/02y72wh86

Funder(s)

Funder type
Research organisation

Funder Name
Physician's Services Incorporated (PSI) Foundation (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	results	01/04/2015		Yes	No