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Evaluation of gabapentin as a pre-emptive analgesic for patients undergoing total hip arthroplasty

Submission date 07/10/2005	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 20/10/2005	**Overall study status** Completed	
Last Edited 13/06/2014	**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

N/A

Study information

Scientific Title

Study objectives
1. Gabapentin administration reduces pain and opioid use postoperatively after total hip arthroplasty
2. Preoperative gabapentin is more effective than postoperative administration. This will definitively demonstrate the pre-emptive analgesic properties of gabapentin.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

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
Pre-emptive pain medication/postoperative pain control

Interventions
This is a prospective, randomized, double-blind, placebo-controlled study to compare total morphine consumption between the pre-emptive gabapentin, the postoperative gabapentin and the placebo groups. Patients will be randomly assigned to one of three treatment arms with 30 patients in each arm. Patients who are randomized to the preoperative gabapentin group will receive 600 mg orally (po) prior to surgery. The other two treatment arms will receive either placebo or gabapentin 600 mg 1 hour after their surgery is complete.

Intervention Type

Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Gabapentin

Primary outcome measure
A comparison of the means of morphine consumption among the various treatment groups will be the primary outcome measure.

Secondary outcome measures
1. Visual Analog Scale (VAS) for pain will be used (0 = no pain, 100 = terrible pain)
2. Presence of nausea, vomiting, pruritis, and dizziness will be monitored at the same time intervals, and all except the latter treated as per the Acute Pain Service Nausea and Vomiting algorithm

Overall study start date
01/01/2006

Completion date
01/12/2006

Eligibility

Key inclusion criteria
Upon obtaining informed consent, patients with American Society of Anesthesiologists physical status I and II, of both genders, scheduled for hip arthroplasty will be recruited for this double-blinded, prospective, randomized, and placebo-controlled study. Patients must also be 1870 years of age.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
90

Key exclusion criteria
1. Patients not providing informed consent
2. Patients less than 18 years of age and greater than 75 years of age

3. Known allergy to any of the medications being used
4. History of drug or alcohol abuse
5. Patients with chronic pain on slow-release preparations of opioid
6. Patients with rheumatoid arthritis
7. Patients with psychiatric disorders
8. Patients unable or unwilling to use patient-controlled analgesia
9. Diabetic patients or those with impaired renal function (creatinine >106)
10. Obese patients (i.e., body mass index [BMI] >40)

Date of first enrolment
01/01/2006

Date of final enrolment
01/12/2006

Locations

Countries of recruitment
Canada

Study participating centre
Department of Anesthesia M3-200
Toronto
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Sponsor information

Organisation
Sunnybrook Health Sciences Centre (Canada)

Sponsor details
Department of Anesthesia M3-200
2075 Bayview Ave.
Toronto
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03wefcv03

Funder(s)

Funder type
Not defined

Funder Name
Not provided at time of registration

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	01/09/2009		Yes	No