

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

Submission date 07/10/2005	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 20/10/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 13/06/2014	Condition category Signs and Symptoms	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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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

Canada

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Sponsor information

Organisation

Sunnybrook Health Sciences Centre (Canada)

Sponsor details

Department of Anesthesia M3-200

2075 Bayview Ave.

Toronto

Canada

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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