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

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

**Plain English summary of protocol**Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

Dr Joseph Kay

#### Contact details

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# Additional identifiers

**Protocol serial number** 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

# Study type(s)

Prevention

#### 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(s)

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

#### Key secondary outcome(s))

- 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

#### 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** 

## Healthy volunteers allowed

No

#### Age group

Adult

## Lower age limit

18 years

#### Sex

All

#### 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
M4N 3M5

# Sponsor information

## Organisation

Sunnybrook Health Sciences Centre (Canada)

#### **ROR**

https://ror.org/03wefcv03

# Funder(s)

# Funder type

Not defined

#### Funder Name

Not provided at time of registration

# **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	01/09/2009	Yes	No
Participant information sheet	Participant information sheet	11/11/2025 11/11/2025	5 No	Yes