

# The short- and long-term effects of perioperative gabapentin use on functional, rehabilitation and pain outcomes following total knee arthroplasty: a randomised, double-blind, placebo-controlled trial

<b>Submission date</b>	<b>Recruitment status</b>	<input checked="" type="checkbox"/> Prospectively registered
03/10/2005	No longer recruiting	<input type="checkbox"/> Protocol
<b>Registration date</b>	<b>Overall study status</b>	<input type="checkbox"/> Statistical analysis plan
25/10/2005	Completed	<input type="checkbox"/> Results
<b>Last Edited</b>	<b>Condition category</b>	<input type="checkbox"/> Individual participant data
13/06/2014	Signs and Symptoms	<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

### Protocol serial number

N/A

# Study information

## Scientific Title

## Study objectives

Perioperative gabapentin is effective in improving in-patient rehabilitation in the acute postoperative period at 6 weeks and possibly 3 months after Total Knee Arthroplasty (TKA) and reduces pain scores associated with rehabilitation.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Ethics approval was received from the local medical ethics committee before trial recruitment began

## Study design

Randomised controlled trial

## Primary study design

Interventional

## Study type(s)

Treatment

## Health condition(s) or problem(s) studied

Rehabilitation medicine and perioperative pain control

## Interventions

Patients will either receive perioperative gabapentin ( $n = 92$ ) for five perioperative days or placebo pills ( $n = 92$ ) for the intervention period within a multimodal analgesic regimen.

Therefore, patients will be given either placebo or gabapentin 600 mg two hours prior to surgery and then either placebo or gabapentin 200 mg twice daily starting 8 hours after their Pre-Operative Dose (POD).

## Intervention Type

Drug

## Phase

Not Applicable

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

Gabapentin

## Primary outcome(s)

1. Does perioperative gabapentin administration positively influence early rehabilitation and recovery of physical function? If so, are these effects maintained at 6 weeks and 3 months post surgery?

2. Does perioperative gabapentin administration reduce postoperative movement evoked pain associated with rehabilitation? If so, are these effects also maintained at 6 weeks and 3 months post surgery?

### **Key secondary outcome(s)**

1. A comparison of the means of morphine consumption between the two groups will be an outcome measures
2. Numeric Rating Scale (NRS) for pain will be used (0 = no pain, 10 = worst possible pain). Data will be collected as described previously
3. Presence of nausea, vomiting, pruritus, 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
4. Sedation, as per the scale described above, at the same time intervals
5. A comparison of the Hospital Anxiety and Depression Scale (HADS) from baseline, POD 4, 6 weeks and 3 months
6. Health-related Quality of Life Scores from the Western Ontario McMaster Universities Osteoarthritis (WOMAC) index

### **Completion date**

08/01/2008

## **Eligibility**

### **Key inclusion criteria**

Upon obtaining informed consent, patients with American Society of Anesthesiologists physical status I and II, of both genders, scheduled for total knee arthroplasty will be recruited for this double-blinded, prospective, randomised, and placebo-controlled study. Patients must also be 18-75 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 (PCA)
9. Diabetic patients or those with impaired renal function (Creatinine >106)
10. Obese patients (i.e., body mass index [BMI] >40)
11. Postoperatively, patients will be excluded if they have had additional operative procedures requiring a change in the usual rehabilitation protocol of care

**Date of first enrolment**

02/01/2007

**Date of final enrolment**

08/01/2008

## 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?
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes