ISRCTN34631378 https://doi.org/10.1186/ISRCTN34631378

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

Submission date 03/10/2005	**Recruitment status** No longer recruiting	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 25/10/2005	**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

Contact name
Dr Joseph Kay

Contact details
Department of Anesthesia M3-200
Sunnybrook Health Sciences Centre
2075 Bayview Ave.
Toronto
Canada
M4N 3M5
+1 416 480 4798
joseph.kay@utoronto.ca

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled 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
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 measure
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?

Secondary outcome measures
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

Overall study start date
02/01/2007

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
184

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)

Sponsor details
Department of Anesthesia M3-200
2075 Bayview Ave.
Toronto
Canada
M4N 3M5

Sponsor type
Hospital/treatment centre

Website
http://mysw.sw.ca/ccm/bins/home.cfm

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