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Postoperative analgesia for total knee replacement: a comparison between intrathecal morphine and peripheral nerve blocks

Submission date 18/10/2006	**Recruitment status** No longer recruiting	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 07/11/2006	**Overall study status** Completed	
Last Edited 07/03/2017	**Condition category** Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Maruthi S R R Ganugapenta

Contact details
50,Milestone Close
Heath
Cardiff
United Kingdom
CF14 4NQ
+44 (0) 2920691036
reddymaruthi@yahoo.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1.

Study information

Scientific Title
Postoperative analgesia for total knee replacement: a comparison between IntraThecal Morphine and Peripheral Nerve Blocks

Acronym
ITM vs PNB

Study objectives
The aim of this study is to compare intrathecal morphine with peripheral nerve block for postoperative analgesia following unilateral primary total knee replacement.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South East Wales Research Ethics Committee, February 2007, ref: 06/WSE04/126

Study design
Double blind randomised controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Analgesia following total knee replacements

Interventions
Spinal Anaesthesia: A fine needle in the lower back. We will give 3 ml of 0.5% heavy Bupivacaine in one group and the same volume in the second group but combined with morphine 7 micrograms/Kg, maximum of 500 microgram.

Femoral 3 in 1 block: In the groin 30 ml of plain Bupivacaine 0.38% will be injected close to the Femoral nerve with a special locator needle. This is done in group one.

Sciatic nerve block: In the buttock 15 ml of 0.38% plain Bupivacaine will be injected close to the Sciatic nerve with the special locator needle.This is also done in group one.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Intrathecal morphine, Tramadol

Primary outcome measure
Quality of pain relief on movement of knee joint.

Secondary outcome measures
The secondary outcome measures include:
1. The number of patients requiring rescue analgesia
2. Time for the first dose of Tramadol
3. The incidence of the adverse effects of Morphine and Visual Analogue Scale (VAS) for patient satisfaction at 48 hours

Overall study start date
01/01/2007

Completion date
31/12/2007

Eligibility

Key inclusion criteria
1. Primary elective total knee replacement
2. Fit patients of American Society of Anesthesiologists (ASA) classification one to three

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
80

Key exclusion criteria
1. Patients who refuse consent
2. Revision surgery
3. Had adverse reaction or a contraindication to the administration of morphine, local anaesthetics, non-steroidal anti-inflammatory drugs, paracetamol, tramadol, centrineuraxial block and peripheral nerve blocks
4. Patient with history of chronic pain other than at the site of joint replacement

5. Used regular strong opioids
6. Renal impairment
7. Liver impairment
8. ASA physical status greater than three

Date of first enrolment
01/01/2007

Date of final enrolment
31/12/2007

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
50,Milestone Close
Cardiff
United Kingdom
CF14 4NQ

Sponsor information

Organisation
Gwent Healthcare NHS Trust (UK)

Sponsor details
c/o Ms Rosamund Howell
Postgraduate Centre
The Friars
Friars Road
Newport
Wales
United Kingdom
NP20 4EZ
+44 (0)1633 238138
Rosamund.howell@gwent.wales.nhs.uk

Sponsor type
Hospital/treatment centre

Website

http://www.wales.nhs.uk/sites3/home.cfm?OrgID=79

ROR
https://ror.org/045gxp391

Funder(s)

Funder type
Government

Funder Name
Royal Gwent Hospital Trust Research and Development (Reg: RD/505/06) - No external funding is necessary

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