

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	☒ Prospectively registered ☐ Protocol
Registration date 07/11/2006	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 07/03/2017	Condition category Surgery	☐ Individual participant data ☐ Record updated in last year

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

Protocol serial number
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

Primary study design

Interventional

Study design

Double blind randomised controlled study

Study type(s)

Treatment

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(s)

Quality of pain relief on movement of knee joint.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration