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

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

# Plain English summary of protocol

Not provided at time of registration

# Contact information

## Type(s)

Scientific

#### Contact name

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# 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

## Study design

Double blind randomised controlled study

## Primary study design

Interventional

## 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