

# Comparison of local anaesthetic nerve blocks that still allow a patient to walk versus standard injection of local anaesthetic, for pain relief after knee joint replacement surgery

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<b>Registration date</b> 14/01/2016	<b>Overall study status</b> Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 06/07/2017	<b>Condition category</b> Signs and Symptoms	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Effective pain relief is very important for recovery and rehabilitation after a knee replacement operation. Ideally, pain relief would allow a patient to move their leg and be able to stand or walk (mobilise) straight away after an operation, without complications. Pain relief is often provided using painkiller tablets, however there is also the option of numbing the painful area by injecting a local anaesthetic around the nerves in the area of pain (nerve block). A new nerve block technique has recently been developed, called the motor sparing knee (MSK) block. This aims to temporarily “numb” the nerves carrying pain signals from the knee, but leave the nerves to the muscles unaffected so a patient can move their leg straight away after a knee replacement operation without much pain. This therefore could have the potential to provide not just better pain relief, but helps with effective physiotherapy after an operation. In this research project this technique will be compared with the established practice of injecting large volumes of local anaesthetics around the knee joint. The aim of this study is to compare the pain relieving effects of MSK block and traditional nerve block following knee replacement surgery.

### Who can participate?

Adults undergoing knee replacement surgery.

### What does the study involve?

Participants are randomly allocated to one of two groups, who both undergo the knee replacement operation under general anaesthetic. For participants in the first group, the surgeon injects the local anaesthetic (chirocaine) into the knee joint in order to provide post-operative pain relief. For participants in the second group, guided using an ultrasound machine for precision, 15ml of 0.5% chirocaine is injected into several specific nerves in the thigh in order to provide post-operative pain relief (MSK block). In the 48 hours following their surgery, participants in both groups are visited by specialist pain nurses who ask them to rate their pain levels. Participants also see a physiotherapist 4 hours after surgery, and then again 1 and 2 days after surgery, in order to measure how long it takes them to mobilise.

What are the possible benefits and risks of participating?

Participants could benefit from lower pain levels, the ability to move their knee and walk sooner, a faster discharge from hospital and being able to return to normal activities in daily life sooner. Also, as the MSK block procedure is ultrasound-guided, there is a lower risk of nerve injury. Risks of taking part in this study are low however there is a remote risk of a first time allergy to the anaesthetic used.

Where is the study run from?

Morrison Hospital, Swansea (UK)

When is the study starting and how long is it expected to run for?

January 2015 to December 2018

Who is funding the study?

Welsh Pain Society (UK)

Who is the main contact?

Dr John Dingley

## Contact information

**Type(s)**

Scientific

**Contact name**

Dr John Dingley

**Contact details**

Department of Anaesthetics

Morrison Hospital

Heol Maes Eglwys

Swansea

United Kingdom

SA6 6NL

## Additional identifiers

**Integrated Research Application System (IRAS)**

151413

**Protocol serial number**

IRAS ID No: 151413

## Study information

**Scientific Title**

Comparison of motor sparing knee (MSK) blocks versus local infiltration in primary total knee replacement (TKR)

**Acronym**

MSK study

## **Study objectives**

Primary objective:

To compare average Numerical Pain Scores over the first 24 hours between the MSK and Local Anaesthetic Infiltration (LAI) groups. We hypothesise that there will be a lower pain score in the MSK group and decreased use of analgesic drugs post-operatively.

Secondary Objectives:

1. To compare opioid usage between the two groups. We hypothesise there will be a reduction in opioid usage in the first 48 hours between the MSK and LAI groups.
2. Time to mobilisation will be reviewed. We hypothesise there will be no delay in time to mobilise between the two groups.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Wales REC 6 Research Ethics Committee, 27/10/2015

## **Study design**

Single-centre double-blind randomised controlled trial

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

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

Pain after knee joint replacement surgery

## **Interventions**

Participants are randomly allocated to one of two groups.

Group 1: Participants will receive a standard general anaesthetic with standard monitoring. In addition, the joint will be infiltrated with the local anaesthetic chirocaine by the surgeon to provide a degree of post-operative pain relief (the standard technique).

Group 2: Participants will receive the same general anaesthesia as Group A as well as receiving an MSK block. This involves injecting a total of 15mls of 0.5% chirocaine into the lateral cutaneous nerve of the thigh (LCNT) running between sartorius and tensor fascia lata, the intermediate cutaneous nerve of thigh (IMCNT) traversing the sartorius muscle just below the femoral triangle and the infra-patellar nerve (IPN) in the subsartorial canal at mid-thigh level. The genicular branches identified deep to vastus lateralis and medialis at the femoral epicondyles and the inferior genicular branch located medial to the tibial plateau will be blocked using 5mls of 0.5% chirocaine each. The posterior capsule is blocked by placing 5mls of 0.5% chirocaine on the deep aspect of the popliteal artery at the level of the knee distal to the sciatic nerve bifurcation.

Post-operatively, pain is assessed using the numeric rating scale (NRS) in all participants. If the pain is recorded as 4 or greater, intravenous morphine is to be titrated at 2mg aliquots until the pain is controlled to a score of 2 or less. If there is a high opioid requirement in recovery (16mg or more) then the anaesthetist will review the patient to assess whether morphine patient controlled analgesia (PCA) is required. Pain will be measured 4 times a day for 48 hours following surgery.

As part of the standard enhanced recovery programme the patient is mobilised on the same day of surgery, preferably after four hours (providing vital signs are stable). Physiotherapists will ensure that patients have adequate motor function prior to mobilisation. Standard physiotherapy assessment charts with some modifications will be utilised to obtain a record of distance walked with aid, ability to hold quadriceps tension/lift leg, range of motion and highest pain score during physiotherapy. This will be repeated by the physiotherapist on postoperative days 1 and 2.

### **Intervention Type**

Other

### **Primary outcome(s)**

Pain will be measured using the Numerical Rating Score of pain over a 48 hour period after surgery collected at 8am, 12pm, 5pm and 10pm on each day.

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

1. Opioid use over the first 48 hours after surgery is recorded by blind assessors throughout each patient's hospital stay
2. Time to mobilisation after surgery will be determined by recording walking distance, ability to complete leg lifts and range of motion during physiotherapy 4 hours post-surgery, 1 and 2 days post-surgery

### **Completion date**

30/06/2016

### **Reason abandoned (if study stopped)**

Objectives no longer viable

## **Eligibility**

### **Key inclusion criteria**

1. Primary knee replacement
2. Aged between 18 to 80 years
3. Able to give valid consent
4. No history of chronic pain unrelated to knee pain
5. No history of extensive trauma to the joint

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. Lack of capacity for consent
2. Neuropathic pain / sensory disorders in leg to be operated on
3. Diabetes Mellitus
4. Previous major bone surgery in the knee to be operated on
5. Intolerance to study drugs
6. Local infection at site of operation
7. Significant GORD
8. BMI greater than 30
9. ASA 4/5
10. Long term opioid usage

**Date of first enrolment**

01/01/2016

**Date of final enrolment**

30/06/2016

**Locations****Countries of recruitment**

United Kingdom

Wales

**Study participating centre****Morrison Hospital**

Anaesthetic Department

Heol Maes Eglwys

Swansea

United Kingdom

SA6 6NL

**Sponsor information****Organisation**

Abertawe Bro Morgannwg University Trust

**ROR**

<https://ror.org/04zet5t12>

## **Funder(s)**

**Funder type**

Other

**Funder Name**

Welsh Pain Society

## **Results and Publications**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

Data sharing statement to be made available at a later date