

# Nurse vs patient management of postop pain

<b>Submission date</b> 22/03/2012	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 22/03/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 11/05/2018	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Total knee replacement (TKR) involves replacing a damaged, worn or diseased knee with an artificial joint. It's a routine operation for knee pain most commonly caused by arthritis. In 2007-8 the NHS undertook over 70,000 TKRs in England and Wales, and the number of TKRs is expected to rise as the population gets older. We know that patients experience significant pain after a TKR operation and this can increase the time taken to get back to walking and normal activities. Pain levels may be changed if the painkillers are taken by the patient when they want to take them (patient-directed self-management of pain) rather than when the nurse gives them as part of a drugs round in hospital (treatment as usual). This study will compare these two methods.

### Who can participate?

Adult patients (aged over 18) undergoing a primary (first) TKR operation.

### What does the study involve?

Participants will be randomly divided into the two groups: patient-directed self-management of pain or treatment as usual. This study will investigate whether patient-directed self-management of pain improves levels of pain at three days after the operation or at discharge (whichever is the sooner) compared to treatment as usual. It will also compare the two groups up to 6 weeks after the operation for satisfaction with control of pain, return to walking and normal activities, any problems, and costs. We will also interview 10 patients and 10 ward staff to explore their experiences of the two methods.

### What are the possible benefits and risks of participating?

It is hoped that the results of this study will help the NHS to improve pain control for patients after TKR. Information from this study may well be relevant to pain control after operations in general.

### Where is the study run from?

Norfolk and Norwich University Hospital NHS Trust (UK).

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

June 2011 to June 2013.

Who is funding the study?  
National Institute of Health Research (NIHR) (UK).

Who is the main contact?  
Prof Simon Donell  
simon.donell@nnuh.nhs.uk

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Simon Donell

**Contact details**  
Consultant Orthopaedic Surgeon & Honorary Professor  
University of East Anglia  
Norfolk and Norwich University Hospital NHS Trust  
Colney Lane  
Colney  
Norwich  
United Kingdom  
NR4 7UY  
+44 (0)1603 287531  
simon.donell@nnuh.nhs.uk

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

**Secondary identifying numbers**  
11157

## Study information

**Scientific Title**  
A randomised controlled trial of patient-directed self-management of pain (PaDSMaP) compared to treatment as usual following total knee replacement.

**Acronym**  
PaDSMaP

**Study objectives**  
To investigate if PaDSMaP reduces pain at 3 days post-operatively or discharge (whichever is sooner) after primary total knee replacement compared to treatment as usual

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Cambridgeshire 1 Research Ethics Committee, 30/12/2010, ref: 10/H0304/52

**Study design**

Open-label 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**

Musculoskeletal disease: Total knee replacement

**Interventions**

Patients self-medicate their oral analgesics post total knee replacement when sufficiently recovered from the anaesthetic. Treatment as usual comparator cohort have analgesics dispensed as per usual by nurses on drug rounds

Follow up length: Six weeks; Study entry: Single randomisation only

**Intervention Type**

Procedure/Surgery

**Primary outcome measure**

Pain levels for patients at three days post-operatively or at discharge (whichever is the sooner) as measure on a non-graded 10cm visual analogue scale (VAS)

**Secondary outcome measures**

1. Pain during inpatient stay and after six weeks post-operatively (non graded 10cm VAS)
2. Satisfaction with pain levels patient questionnaire
3. Satisfaction with Information About Medicines Scale (SIMS)
4. EuroQOL EQ-5D questionnaire (EQ-5D)
5. Oxford Knee Score (OKS)
6. Time to mobilisation after operation (e.g. day on which patient was able to stand up and transfer from bed to chair)

7. Medication usage (Inpatient Prescription Chart and CRF)
8. Adverse events (CRF)
9. A health resources questionnaire
10. Qualitative evaluation of patient's and health professionals' experiences

**Overall study start date**

30/06/2011

**Completion date**

30/06/2013

## Eligibility

**Key inclusion criteria**

1. All adult patients (e.g. aged over 18) undergoing a primary total knee replacement operation
2. Must meet the Norfolk and Norwich University Hospital NHS Foundation Trust self-management of pain criteria
3. Are expected to require standard step 1-3 oral analgesics post-operatively (WHO 2009)
4. Post-operatively, patients must be awake and breathing independently, able to answer questions and follow commands to continue in the protocol
5. Are English speaking and literate (we expect patient participants to be able to read the information sheet and fill in a number of self-assessments)
6. Patients may have received regional blocks or epidural analgesia, and will start PaDSMaP or TAU as soon as they begin oral analgesia

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

Planned Sample Size: 144; UK Sample Size: 144

**Key exclusion criteria**

1. Expected to require intensive care
2. Known or suspected to be opioid tolerant or dependent
3. Regular users of any modified release opiate preparation for > two weeks prior to total knee replacement
4. Recent history of drug or alcohol abuse
5. Patients who lack competence to consent by reason or dementia or any other reason
6. Any patient who does not self-administer at home

**Date of first enrolment**

30/06/2011

**Date of final enrolment**

30/06/2013

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

Norfolk and Norwich University Hospital NHS Trust

Norwich

United Kingdom

NR4 7UY

## **Sponsor information**

**Organisation**

Norfolk and Norwich University Hospital NHS Trust (UK)

**Sponsor details**

c/o Ms Kathryn Andrews

Colney Lane

Colney

Norwich

England

United Kingdom

NR4 7UY

+44 (0)1603 286286

kathryn.andrews@nnuh.nhs.uk

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.nnuh.nhs.uk/>

**ROR**

<https://ror.org/01wspv808>

# Funder(s)

## Funder type

Government

## Funder Name

National Institute of Health Research (NIHR) Research for Patient Benefit (RfPB) (UK) ref: PB-PG-1208-18121

# 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

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>	protocol	05/11/2012		Yes	No
<a href="#">Results article</a>	results	10/05/2018		Yes	No