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Nurse vs patient management of postop pain

Submission date
22/03/2012

Recruitment status
No longer recruiting

Registration date
22/03/2012

Overall study status
Completed

Last Edited
11/05/2018

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 sufficently 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?
Protocol article	protocol	05/11/2012		Yes	No
Results article	results	10/05/2018		Yes	No