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Evaluation of an intervention to improve post-operative sleep and pain control in orthopaedic patients at night.

Submission date 23/01/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 23/01/2004	**Overall study status** Completed	
Last Edited 21/01/2010	**Condition category** Signs and Symptoms	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

9502049

Study information

Scientific Title

Study objectives
Post-operative pain control has frequently been shown to be poor in British hospitals. The particular problems of assessing and controlling pain at night have been neglected. This study aims to evaluate the effectiveness of a two pronged intervention. The first part will consist of a patient education package designed to inform patients about what to expect concerning their pain and its management, and to improve their willingness to report post-operative pain at night. The second will introduce to nurses a method for assessing pain at night. Orthopaedic patients from two wards will be invited to participate. After a period of baseline data collection the intervention will be introduced to one of the wards (assigned randomly), and its effectiveness evaluated.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet

Health condition(s) or problem(s) studied
Post operative pain

Interventions
1. Patient education package designed to inform patients about what to expect concerning their pain and its management, and to improve their willingness to report post-operative pain at night.
2. The second will introduce to nurses a method for assessing pain at night.

Intervention Type

Other

Phase
Not Specified

Primary outcome measure
Outcomes of night-time pain control will be elicited from patients using verbal rating scales, reports of sleep and analgesic provision.

Secondary outcome measures
Not provided at time of registration

Overall study start date
09/01/1995

Completion date
31/10/1997

Eligibility

Key inclusion criteria
1. Two matched orthopaedic wards at a large teaching hospital
2. Elective and trauma patients
3. Aged 18+ years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
417 (added 21/01/10; see publication)

Key exclusion criteria
1. Permanent night-shift workers
2. Suffering concomitant terminal disease
3. Confused or cognitively impaired

Date of first enrolment
09/01/1995

Date of final enrolment
31/10/1997

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
School of Healthcare Studies
Leeds
United Kingdom
LS2 9LN

Sponsor information

Organisation
NHS R&D Regional Programme Register - Department of Health (UK)

Sponsor details
The Department of Health
Richmond House
79 Whitehall
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United Kingdom
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+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
NHS Executive Northern and Yorkshire (UK)

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?
Results article	results	01/02/1999		Yes	No
Other publications	secondary analysis	01/12/1999		Yes	No