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Care pathway for total knee replacement: a prospective single blind randomised controlled trial.

Submission date 12/09/2003	**Recruitment status** Stopped	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 12/09/2003	**Overall study status** Stopped	
Last Edited 22/08/2011	**Condition category** Surgery	

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
N0050114601

Study information

Scientific Title

Study objectives
Are patients' outcomes improved by the use of a care pathway in total knee replacement?

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)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Surgery: Total knee replacement (TKR)

Interventions
A prospective randomised controlled trial of a care pathway for a total knee replacement versus current best clinical care. It is not possible for clinical staff to be blind to the condition in which they are participating. However, we contend that patients will be unaware of whether a care pathway is a novel organisation of care and so will be unaware of whether they have been allocated to the novel or usual treatment condition.

Added September 2008: trial stopped in August 2004 as wards within the hospital were reconfigured which meant randomisation was not possible.

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome measure
The main outcome measure will be length of stay in hospital.

Secondary outcome measures
Secondary measures will be: adequacy of pain control, readmission rate and patient satisfaction as measured by an audit tool currently used within the Trust.

Overall study start date
05/08/2002

Completion date
31/07/2003

Reason abandoned (if study stopped)
Objectives no longer viable

Eligibility

Key inclusion criteria
100 women undergoing knee replacement surgery in Bradford Royal Infirmary Wards 3 and 5 who consent to participate in the study. Confining the study to women allows us to randomise between the two local settings, since only one setting deals with both sexes. 69% of knee replacement operations within the Trust are female. This percentage also reflects national and international trends. Mean age locally for this procedure is 69 years.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
100

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
05/08/2002

Date of final enrolment
31/07/2003

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
School of Health Studies
Bradford
United Kingdom
BD5 0BB

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

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

Funder(s)

Funder type
Government

Funder Name
Bradford Hospitals NHS Trust (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