

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

Submission date 12/09/2003	Recruitment status Stopped	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/09/2003	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 22/08/2011	Condition category Surgery	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

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