

The effectiveness of patient-reported outcome measures (PROMs) in improving the quality of care for patients undergoing hip replacement surgery

Submission date 17/06/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 28/07/2011	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 12/08/2016	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

All patients in England who are having hip replacement surgery are invited to complete a Patient Reported Outcome Measures (PROMs) questionnaire before and six months after their operation. The NHS in England developed this initiative in order to improve the quality of the care that it provides. In Ireland, surgeons' performance data lacks both the patients' view and outcome measures. The aim of this study is to find out whether collecting patient-reported outcomes from hip replacement patients and feeding the results back to surgeons is effective at improving patient outcomes.

Who can participate?

Orthopaedic surgeons and patients aged over 18 undergoing hip replacement surgery

What does the study involve?

Patients are asked to complete a questionnaire before and six months after their hip replacement surgery. Surgeons are randomly allocated to one of three groups. The first group receives no feedback on outcome scores. The second group receives feedback and an educational session covering interpretation of the data. The third group receives the same as the second group but with additional information to improve their interpretation of the data.

What are the possible benefits and risks of participating?

Not provided at time of registration

Where is the study run from?

1. AMNCH, Tallaght
2. Cappagh National Orthopaedic Hospital, Dublin
3. St. Mary's Orthopaedic Hospital, Cork
4. Croom Regional Orthopaedic Hospital, Limerick
5. Lourdes Orthopaedic Hospital, Kilkenny

6. Our Lady's Hospital, Navan
7. Tullamore Regional Hospital, Offaly
8. Merlin Park Regional Hospital, Galway
9. Bon Secours Hospital, Cork
10. Bon Secours Hospital, Dublin
11. Bon Secours Hospital, Galway
12. Blackrock Clinic, Dublin
13. Hermitage Medical Clinic, Dublin
14. Sports Surgery Clinic, Dublin
15. The Beacon Medical Clinic, Dublin

When is the study starting and how long is it expected to run for?
April 2011 to May 2013

Who is funding the study?
The Health Research Board (Ireland)

Who is the main contact?
Prof. John Browne
J.Browne@ucc.ie

Contact information

Type(s)
Scientific

Contact name
Prof John Browne

Contact details
Dept. of Epidemiology and Public Health
Brookfield Health Sciences Complex
University College Cork
Cork
Ireland
N/A
+353 (0)21 490 1598
J.Browne@ucc.ie

Additional identifiers

Study information

Scientific Title
Does providing patient-reported outcome feedback to orthopaedic surgeons improve outcomes for patients undergoing hip replacement surgery compared to providing no feedback? A cluster randomised controlled trial

Acronym
PROFILE

Study objectives

PROFILE (Patient Reported Outcomes: Feedback, Interpretation and Learning Experiment)

1. Providing feedback with benchmarking of PROMs data to surgeons will improve outcomes for patients undergoing hip replacement surgery.
2. Using methods to improve the interpretability of PROMs will further improve outcomes for patients undergoing hip replacement surgery.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Clinical Research Ethics Committee, University College Cork, 07/12/2010

Study design

Multi-centre cluster randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Osteoarthritis/primary hip replacement surgery

Interventions

Participating surgeons will be randomly assigned by an independent person who has no patient or physician contact to one of three groups using a computer generated list of random permuted blocks of numbers. The three arms of the trial are:

1. No feedback on outcome scores (control group).
2. Feedback plus educational session covering benchmarking and interpretation of data (intervention group 1)
3. As intervention group 1 but with additional use of Rasch analysis to improve interpretability of the data (Intervention group 2)

Blinding of surgeons will not be possible, however blinding of patients and those carrying out statistical analyses will be used.

This study will involve a quality improvement package based upon PROMs including a feedback report and an educational session. The type of feedback report will depend on the intervention group and will contain personalised PROMs data for each surgeon. The feedback will be benchmarked against UK PROM data and anonymous Irish peer data to eliminate contamination and confidentiality issues. The educational session will be provided to the intervention groups and will describe the content, scoring and interpretation of the PROMs data. Intervention group 2 will be provided with additional information regarding Rasch analysis.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

The Oxford hip score. It is widely used specific instrument to estimate outcomes after hip replacement. It has shown to be responsive to change and is the disease-specific instrument used in the UK PROMs programme. This data will be captured before the operation and at six months after the operation.

Key secondary outcome(s)

1. The EQ-5D score
2. The Hip Osteoarthritis Outcome Score
3. Surgical complication rate

Measured before the operation and at six months after the operation

Completion date

31/05/2013

Eligibility**Key inclusion criteria**

Surgeon:

High volume hip replacement surgeons (defined as at least two primary, unilateral, elective hip replacement operations per week)

Patient:

1. Aged over 18
2. Undergoing primary, unilateral, elective hip replacement surgery
3. Public and private patients

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

Surgeon:

1. Low volume hip replacement surgeons
2. Near retirement (in next 2 years)

Patient:

1. Aged under 18
2. Undergoing a bilateral or revision hip replacement
3. Surgery due to trauma
4. Unable to complete a written questionnaire in English be it due to: cognitive impairment, literacy or language comprehension

Date of first enrolment

01/04/2011

Date of final enrolment

31/05/2013

Locations

Countries of recruitment

Ireland

Study participating centre

University College Cork

Cork

Ireland

N/A

Sponsor information

Organisation

The Health Research Board (Ireland)

ROR

<https://ror.org/003hb2249>

Funder(s)

Funder type

Government

Funder Name

Health Research Board

Alternative Name(s)

Health Research Board, Ireland, An Bord Taighde Sláinte, HRB

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Ireland

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary****Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	31/07/2015		Yes	No