

Introducing standardized and evidence-based thresholds for hip and knee replacement surgery

Submission date 01/11/2013	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 22/11/2013	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 17/08/2020	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Patients for hip and knee replacement are referred by general practitioners (GPs) in primary care to secondary care (hospital) when it is felt patients symptoms are severe, unremitting (no change in symptoms) and disabling. In secondary care patients have further assessment and a decision to proceed to surgery is made. UK data shows widespread regional variation in the way patients are selected for surgery. In addition, 15% of patients having these interventions are dissatisfied with their outcome. One of the reasons suggested for the variation and dissatisfaction is the way in which patients are deemed suitable for hip or knee surgery. An evidence-based system, developed from a currently used assessment tool, could be introduced for GPs and hospital teams to use. Using the system, patients who are highly likely to benefit from surgery could be identified and referred, whilst those who would not benefit from surgery can be guided to other treatment options. We will meet explore which established hip and knee assessment tools can be used to determine safe, cost-effective thresholds for treatment, based on patients capacity to improve. In doing this, our aim is to provide the NHS with a universal, valid, cost-effective and fair system for selecting patients for joint replacement. We will achieve this by creating the Arthroplasty Candidacy Help Engine (ACHE) tool. The ACHE tool will consist of a combination of a currently available clinical questionnaire and a set of thresholds, by which patients who would benefit from surgery are identified and referred on to secondary care.

Who can participate?

Patients over 18 with knee or hip osteoarthritis.

What does the study involve?

Our research programme involves three stages. In the first stage, work package (WP) 1, we will conduct a comprehensive literature review and assessment of measurement properties of current clinical tools used for assessing patients with osteoarthritis and/or undergoing joint replacement surgery. In the second stage, WP2, we will calculate preoperative threshold levels for three short-listed candidate tools to identify patients who are candidates for surgery which will be the best at identifying which patients can benefit most from surgery and to find the optimum cost effectiveness. In the third stage we will evaluate the effect of the ACHE tool and

its acceptance by stakeholders, such as patients, GPs, doctors and commissioners. We will evaluate the impact of the new ACHE tool by applying it to a series of patients being considered for referral to secondary care, via our hub referral centre in Oxford. We estimate that the tool will demonstrate its effectiveness by identifying patients who have been appropriately referred, but also a group of patients who would not benefit from surgery and who should not have been referred. In the second part of WP3 we will obtain, via questionnaires, the views of a large number of GPs and patients as to the acceptability of the ACHE tool. Thirdly, in WP3, we will formally consult with an extended group of stakeholders who are involved in the pathway for hip and knee surgery within the NHS (patients, healthcare professionals and commissioners of services) and present the evidence we have compiled. Across each stage a USER Group consisting of stakeholder representatives (patients, public, GPs, secondary care health care workers, surgeons and commissioners) will be actively involved in the research process.

What are the possible benefits and risks of participating?

There are no risks or immediate benefits to participants in this study.

Where is the study run from?

This study is a collaboration between the University of Oxford, the University of Bristol and Peninsula Medical School. The research will be led from Oxford (Nuffield Orthopaedic Centre) but workers will be based in the Avon Orthopaedic Centre (Bristol) and Peninsula.

When is the study starting and how long is it expected to run for?

The study will start in December 2013 and will run for 36 months.

Who is funding the study?

National Institute for Health Research, UK.

Who is the main contact?

Kristina Harris

kristina.harris@ndorms.ox.ac.uk

Contact information

Type(s)

Scientific

Contact name

Prof Andrew Price

Contact details

The Botnar Research Centre Institute of Musculoskeletal Sciences
University of Oxford
Nuffield Orthopaedic Centre
Windmill Road
OXFORD
United Kingdom
OX3 7LD

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

HTA: 11/63/01

Study information

Scientific Title

Introducing standardized and evidence-based thresholds for hip and knee replacement surgery: the Arthroplasty Candidacy Help Engine (the ACHE tool)

Acronym

ACHE

Study objectives

The overall aim of this project is to develop a standardized NHS framework for identifying patients for hip and knee replacement surgery using safe and equitable thresholds by creating the ACHE (Arthroplasty Candidacy Help Engine) tool, based on a currently available assessment score, with thresholds that take account of patients capacity to benefit from surgery and the cost-effectiveness of the treatment. The new system will be applicable in both primary and secondary care.

More details can be found at: <http://www.nets.nihr.ac.uk/projects/hta/116301>

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at the time of registration. The ethics approval for the surveys will be required at year 3 of the study. The application will be submitted to the Oxfordshire REC.

Study design

Observational study (cross-sectional survey)

Primary study design

Observational

Secondary study design

Cross-section survey

Study setting(s)

Hospital

Study type(s)

Screening

Participant information sheet

Patient information material will be available in year 3 of this study, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Hip and knee osteoarthritis

Interventions

This study consists of three work packages (WPs).

The aim of WP1 is to identify pre-existing assessment tools that could be used to create referral thresholds for hip and knee replacement surgery. This will be done by performing a literature review to assess the measurement properties of the existing tools and using the existing datasets to further characterize the measurement properties of the candidate tools.

The aim of WP2 is to create the Arthroplasty Candidacy Help Engine (ACHE) tool, with thresholds for referral based on capacity to benefit and health-economic benefit. This will be done by defining a range of preoperative thresholds which would act as predictors of postoperative success for each candidate score. Furthermore, we will look at the effect of threshold values on the cost effectiveness of hip and knee replacement.

In WP3, we will assess the likely impact, acceptability and feasibility of introducing the ACHE tool within the NHS, using three different approaches. First, we will assess the likely impact of using the ACHE tool on patients referral to secondary care, by applying retrospectively the ACHE tool to a series of 400 patients who have been referred to our Integrated Care and Treatment hub. We will demonstrate the impact of the ACHE tool by calculating the percentage of patients who would not have been referred if the ACHE tool had been applied in primary care. Then we will use questionnaires to ask the opinion of 348 GPs and 271 patients regarding the proposed usage of the ACHE tool, focusing on its content, means of use and acceptability. Finally we will use a broad stakeholder consultation group, using deliberative methods of stakeholder engagement to further explore acceptability/feasibility and to deliver a consensus about use of the ACHE tool, identifying thresholds that are acceptable to stakeholders. The Group will meet twice, with two months between meetings.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

A structured literature review will be conducted to identify and compare the measurement properties of candidate tools that have been evaluated for use with patients suffering from osteoarthritis/undergoing joint replacement surgery.

Secondary outcome measures

No secondary outcome measures

Overall study start date

01/12/2013

Completion date

01/12/2016

Eligibility

Key inclusion criteria

General practitioners and patients with knee or hip osteoarthritis/replacement

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

271 patients and 348 general practitioners

Key exclusion criteria

Patients under 18

Date of first enrolment

01/12/2013

Date of final enrolment

01/12/2016

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

The Botnar Research Centre Institute of Musculoskeletal Sciences

OXFORD

United Kingdom

OX3 7LD

Sponsor information

Organisation

University of Oxford

Sponsor details

Research Services
Clinical Trial and Research Governance
Joint Research Office
Block 60
Churchill Hospital
Headington
Oxford
England
United Kingdom
OX3 7LE

Sponsor type

University/education

Website

<http://www.ox.ac.uk/>

ROR

<https://ror.org/052gg0110>

Funder(s)**Funder type**

Government

Funder Name

NIHR Health Technology Assessment Programme - HTA (UK) 11/63/01

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 results	Date created	Date added	Peer reviewed?	Patient-facing?
-------------	--------------------	--------------	------------	----------------	-----------------

[Results article](#)

01/06/2019

17/08/2020

Yes

No