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Arthroplasty Pain Experience (APEX) Study

Submission date
29/04/2010

Recruitment status
No longer recruiting

Registration date
29/04/2010

Overall study status
Completed

Last Edited
04/01/2016

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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
7664

Study information

Scientific Title

A randomised controlled trial to determine if local wound infiltration reduces chronic pain after lower limb arthroplasty

Acronym
APEX study

Study objectives
Joint replacement is one of the most common elective surgical procedures performed in the NHS. However, previous research indicates that between 10 - 30% of patients experience chronic pain after hip and knee replacement. Therefore, more research is required to explore methods of minimising chronic pain after joint replacement. The aim of this study is to determine whether an injection of local anaesthethic into the hip or knee during joint replacement surgery, in addition to standard anaesthetic, reduces long-term pain.

To do this, 300 patients listed for knee replacement and 300 patients listed for hip replacement at the Avon Orthopaedic Centre will be recruited into a randomised controlled trial. Participants will complete questionnaires to assess their joint pain and function, psychological status, and use of healthcare resources. Participants will complete questionnaires before their operation, and then at regular intervals after their operation, while they are an in-patient.

Following discharge from hospital, participants will be asked to complete postal questionnaires at 3-months and 6-months after surgery. At 12-months after surgery, participants will be asked to complete a final questionnaire and undergo a joint assessment with a research nurse. Also a small number of participants and health care professionals will be interviewed about their participation in the study, in order to find out how participation in the trial affects them.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Southampton and South West Hampshire REC (B), 27/08/2009, ref: 09/H0504/94

Study design
Randomised interventional treatment trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Musculoskeletal; Subtopic: Musculoskeletal (all Subtopics); Disease: Musculoskeletal

Interventions
Participants randomised to the interventional arm of the trial will receive a local wound infiltration, in addition to the standard anaesthetic regimen during surgery. The local anaesthetic mixture will consist of 60 ml of 0.25% bupivicaine with 1 in 200,000 adrenaline.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The WOMAC Pain score at 12-months post-operative.

Secondary outcome measures
1. Length of hospital stay
2. Daily 100mm Visual Analogue Scale (VAS) ratings while an in-patient (starting the day after surgery until discharge or day 5 after surgery)
3. Western Ontario and McMaster Universities Arthritis Index (WOMAC) Function and Stiffness Scale
4. Intermittent and Constant Osteoarthritis Pain (ICOAP) pain measure
5. Pressure pain thresholds of the volar forearm will be measured using pressure algometry pre-operatively, at discharge from hospital and 12-month and post-operative
6. Resource use: Health service resource use including staff time and other resources used in the intervention, inpatient stays, outpatient visits and general practitioner visits, will be collected using hospital records and participant self-completed questionnaires (including the EQ-5D). These questionnaires will be administered at 3, 6 and 12 months post-operatively and will also be used to measure the time and travel of the patient and the carer if applicable.

Overall study start date
25/11/2009

Completion date
01/09/2010

Eligibility

Key inclusion criteria
1. Patients undergoing primary total hip replacement or primary total knee replacement for osteoarthritis at the Avon Orthopaedic Centre
2. Are willing and able to provide fully informed consent and complete the study questionnaires
3. Male and female, lower age limit of 18 years

Participant type(s)
Patient

Age group

Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 600

Key exclusion criteria
1. Patients undergoing revision joint replacement
2. Patients undergoing joint replacement for a diagnosis other than osteoarthritis
3. Patients under the age of 18 years
4. Patients with any medical comorbidity that precludes spinal anaesthetic, regional blocks or the use of strong analgesics postoperatively
5. Diagnosis of severe dementia or psychiatric illness such that they are unable to complete the questionnaires or provide informed consent
6. Patients undergoing stimulatenous bilateral joint replacement
7. Patients who have been in the trial for a previous joint replacement
8. Patients who are unable to understand English will be exclude because not all the validated questionnaires have been translated into languages other than English

Date of first enrolment
25/11/2009

Date of final enrolment
01/09/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Southmead Hospital
Bristol
United Kingdom
BS10 5NB

Sponsor information

Organisation
Southmead Hospital (UK)

Sponsor details
Southmead Road
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Sponsor type
Hospital/treatment centre

Website
http://www.nbt.nhs.uk/

ROR
https://ror.org/05d576879

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Central Commissioning Facility (CCF)

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	26/02/2011		Yes	No
Results article	results	26/06/2015		Yes	No
HRA research summary			28/06/2023	No	No