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Preventing Impingement in Total Hip Arthroplasty

Submission date
28/02/2013

Recruitment status
No longer recruiting

Registration date
20/03/2013

Overall study status
Completed

Last Edited
20/03/2013

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
This study aims to address two problems related to total hip replacement: dislocation and wear. Dislocation occurs at rate of about 1-3%, usually in the first few weeks after surgery. Wear of the ball socket bearing surfaces is an unavoidable consequence of movement, but excessive wear produces tiny particles of plastic from the socket which irritate the surrounding tissue and are the most important cause of loosening, late pain and need for revision surgery years later. Such revisions are necessary in at least 20% of people after 20 years.
Both dislocation and excessive wear are frequently caused by impingement between the neck of the femoral (thigh bone) prosthesis just below the ball, and the rim of the acetabular cup (or socket of the joint). This impingement may occur as a result of an extreme range of movement of the hip in the patient, but is much more usually due to the relative positions of the femoral and acetabular components. A different design of hip replacement, in common use in the UK, has a modular neck which allows the surgeon to choose the neck shape (version, length and angle) which best fits the patient during the operation.
We hypothesis that this will give the surgeon the flexibility to avoid impingement, and hence to minimize subsequent dislocation and excessive wear. This study aims to determine if a hip implant with an interchangeable neck component will result in less impingement compared to standard implant with a fixed neck component.

Who can participate?
All adults from both sexes suitable for primary un-cemented total hip replacement by surgeons at University Hospitals of Coventry and Warwickshire will be approached to consider participation. Potential participants will be excluded if they have pelvic or lumbar spine deformity, if they have had previous extensive surgery (such as osteotomy).

What does the study involve?
Potential participants will be included if they consent to take part. Hundred and eight participants will be randomly allocated to one of two groups: total hip replacement procedure using an implant with non-modular neck or using an implant with a modular neck.
Prior to the operation a research physiotherapist will test hip function using a questionnaire called the Oxford Hip score, measure leg length and range of movement. Patients will also be asked to fill out a EuroQol quality of life questionnaire and a disability rating index.

Participants will be followed-up at six weeks then at a twelve month period. It is our intention to follow patients up on an annual basis following the initial year in the study. The results of this long term follow-up will provide us with valuable information about how well the different implants function over a long period of time.
What are the possible benefits and risks of participating?
We do not know which of the two treatments gives the best results. Since both treatments involve surgery, the risks for both groups are the same and equal to individuals who do not take part. There are no special risks over and above what a surgeon would normally inform the patient. Both types of hip implants are currently being used during total hip replacement surgery. There is no specific advantage to the patient for taking part in the study. However the information obtained from this study may help us to decide whether the use of a modular neck implant in total hip replacement will reduce the risk of impingement.

Where is the study run from?
The study will be run collaboratively at the University of Warwick and University Hospitals of Coventry and Warwickshire (UK).

When is the study starting and how long is it expected to run for?
The study started in January 2009 and we aim to complete it by September 2020.

Who is funding the study?
The Study is funded by Wright Medical Limited.

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Version 3

Study information

Scientific Title
Preventing Impingement in Total Hip Arthroplasty: a randomised controlled trial

Acronym
PITHA

Study objectives
Does the use of an uncemented stem with a modular neck component during total hip arthroplasty surgery reduce the risk of prosthetic impingement compared to an identical stem with a non-modular neck?

Ethics approval required
Old ethics approval format

Ethics approval(s)
This Study was approved by the Coventry Research Ethics Committee on the 2nd of October 2007 under reference number 07/Q2802/58.
Amendment 1 approved 18th June 2008
Amendment 2 approved 18th March 2009
Amendment 3 approved 28th October 2011

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Hip osteoarthritis

Interventions

Patients will be randomly assigned to a total hip replacement procedure using an implant with non-modular neck or using an implant with a modular neck.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The proportion of patients in each group who have calculated impingement (calculated in virtual model from the precise orientation of that patient`s hip replacement measured during surgery) inside the intended impingement-free range of movement.

Measured at baseline, six week and twelve months.

Secondary outcome measures
1. Oxford Hip Score
2. UCLA
3. EuroQol EQ-5D
4. Disability rating index
5. Clinical leg length and Range of Movement
6. Analysis of lysis / ingrowth patterns in Gruen zones (using AP pelvis for hips and lateral radiographs

Measured at baseline, six week and twelve months.

Overall study start date
01/01/2009

Completion date
30/09/2020

Eligibility

Key inclusion criteria
1. Patients aged older than 18 years, either sex who are able to give informed consent
2. Patients undergoing primary total hip replacement with a cementless femoral stem.
3. Patients who are physically fit to undergo surgery

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex

Not Specified

Target number of participants
108

Key exclusion criteria
1. Patients with concomitant medical problem that will preclude operation
2. Patients with abnormal hip anatomy
3. Patients with spinal deformity

Date of first enrolment
01/01/2009

Date of final enrolment
30/09/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Division of Health Sciences
Coventry
United Kingdom
CV2 2DX

Sponsor information

Organisation
University of Warwick (UK)

Sponsor details
c/o Dr Peter Hedges
Research Support Services
University House
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England
United Kingdom
CV4 8UW

Sponsor type
University/education

Website
http://www2.warwick.ac.uk/

ROR
https://ror.org/01a77tt86

Funder(s)

Funder type
Industry

Funder Name
Wright Medical Limited (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