

Preventing Impingement in Total Hip Arthroplasty

Submission date 28/02/2013	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 20/03/2013	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 20/03/2013	Condition category Musculoskeletal Diseases	☐ 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

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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s))

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.

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Not Specified

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

United Kingdom

England

Study participating centre

Division of Health Sciences

Coventry

United Kingdom

CV2 2DX

Sponsor information

Organisation

University of Warwick (UK)

ROR

<https://ror.org/01a77tt86>

Funder(s)

Funder type

Industry

Funder Name

Wright Medical Limited (UK)

Results and Publications

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

Not provided at time of registration