# Preventing Impingement in Total Hip Arthroplasty

Submission date	Recruitment status	Prospectively registered
28/02/2013	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
20/03/2013	Completed	Results
<b>Last Edited</b> 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? Dr Juul Achten
J.Achten@warwick.ac.uk

# Contact information

# Type(s)

Scientific

#### Contact name

Prof Damian Griffin

#### Contact details

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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 Coventry 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