# Investigator Initiated Depuy Replacement knee In-Vivo Evaluation Study

Submission date	Recruitment status	[X] Prospectively registered		
12/08/2010	No longer recruiting  Overall study status	∐ Protocol		
Registration date		Statistical analysis plan		
08/10/2010  Last Edited	Completed  Condition category	☐ Results		
		Individual participant data		
04/10/2017	Musculoskeletal Diseases	Record updated in last year		

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

Dr Anthony Redmond

#### Contact details

Leeds Institute for Molecular Medicine Section of Musculoskeletal Disease 2nd Floor, Chapel Allerton Hospital Harehills Lane Leeds United Kingdom LS7 4SA

# Additional identifiers

**EudraCT/CTIS** number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Version 1.1

# Study information

#### Scientific Title

Investigator Initiated Depuy Replacement knee In-Vivo Evaluation Study: a post-operative comparator study characterising the in-vivo functional capacities of patients following total knee arthroplasty (TKA) after randomisation to one of two different implant types

#### Acronym

**DRIVE** 

### Study objectives

To compare the in-vivo function of the PFC sigma cruciate retaining (CR) implant with the PFC CR 150 at 3, 6 and 12 months post-operatively.

## Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Leeds West Research Ethics Committee, 01/02/2010, ref: 09/H1307/103

#### Study design

Post-operative comparator randomised controlled 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

Osteoarthritis

#### Interventions

A total of 40 patients will be recruited to the study. These patients will undergo a range of baseline evaluations as appropriate to their presenting condition. These would include:

- 1. A routine musculoskeletal clinical examination (including assessment of presenting symptoms and clinical musculoskeletal functional tests)
- 2. Completion of relevant patient reported outcome instruments (36-item short form health survey [SF-36], Oxford knee score, Knee Injury and Osteoarthritis Outcome Score [KOOS], Knee Society Clinical Rating System [KSS])

- 3. Knee joint kinematics and kinetics measured using Vicon T series, Oxford Metrics Oxford UK
- 4. Functional measures to be undertaken include:
- 4.1. High flexion angle joint function measured using Fastrak electromagnetic motion tracking (Polhemus, USA)
- 4.2. High demand joint function (Sit to stand and squat) measured using Vicon T series (Oxford Metrics Oxford, UK)

A case/control design will be used to compare outcomes following surgery in patients receiving PFC sigma and CR150 implants. Patients will undergo the same range of evaluations as those described above at 3 months, 6 months and 1 year.

#### Intervention Type

Other

#### Phase

Not Applicable

#### Primary outcome measure

Maximum knee flexion measured using the Fastrak electromagnetic motion tracking system (Polhemus, USA)

#### Secondary outcome measures

A comparison of high performance activities (sit to stand and squatting) 12 months after surgery

#### Overall study start date

01/11/2010

## Completion date

30/09/2012

# **Eligibility**

#### Key inclusion criteria

- 1. Patients (no age limit, either sex) with osteoarthritis of the knee undergoing unilateral knee replacement at Chapel Allerton Orthopaedic Centre
- 2. Patients with a functionally normal contralateral knee

# Participant type(s)

Patient

## Age group

All

#### Sex

Both

## Target number of participants

40

# Key exclusion criteria

- 1. Patients who cannot safely walk unaided
- 2. Patients who decline to give permission for their clinical data to be used in anonymised form for research purposes
- 3. Patients who are unable to give informed consent

#### Date of first enrolment

01/11/2010

#### Date of final enrolment

30/09/2012

# Locations

#### Countries of recruitment

England

**United Kingdom** 

# Study participating centre Leeds Institute for Molecular Medicine

Leeds United Kingdom LS7 4SA

# Sponsor information

# Organisation

University of Leeds (UK)

# Sponsor details

Woodhouse Lane Leeds England United Kingdom LS2 9JT

#### Sponsor type

University/education

#### Website

http://www.leeds.ac.uk/

#### **ROR**

https://ror.org/024mrxd33

# Funder(s)

# Funder type

Industry

#### **Funder Name**

DePuy International 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

# **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No