# 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	Completed  Condition category	☐ Results		
Last Edited		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

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## Additional identifiers

#### Protocol serial number

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

#### Study type(s)

**Treatment** 

#### 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(s)

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

#### Key secondary outcome(s))

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

#### 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** 

## Healthy volunteers allowed

No

#### Age group

All

#### Sex

All

#### 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

United Kingdom

England

#### Study participating centre

## Leeds Institute for Molecular Medicine

Leeds United Kingdom LS7 4SA

# Sponsor information

#### Organisation

University of Leeds (UK)

#### ROR

https://ror.org/024mrxd33

# Funder(s)

#### Funder type

Industry

#### Funder Name

DePuy International Limited (UK)

## **Results and Publications**

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes