

Investigator Initiated Depuy Replacement knee In-Vivo Evaluation Study

Submission date 12/08/2010	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 08/10/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 04/10/2017	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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/024mrx33>

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