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Investigator Initiated Depuy Replacement knee In-Vivo Evaluation Study

Submission date	Recruitment status	[X] Prospectively registered
12/08/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
08/10/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] 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

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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