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Functional outcome in two different designs of knee replacements

Submission date	Recruitment status	[ ] Prospectively registered
19/05/2008	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
24/07/2008	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
09/11/2012	Musculoskeletal Diseases	

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
N/A

Study information

Scientific Title
A randomised controlled trial to compare the functional outcome between the PFC Sigma fixed bearing posterior cruciate ligament (PCL) preserving implant with the PFC Sigma posterior stabilised mobile bearing implant

Study objectives
The aim of this study is to compare the functional outcome of the cruciate substituting PFC Sigma rotating platform flexion (RPF) implant with the cruciate retaining PFC Sigma cruciate retaining (CR) in patients with osteoarthritis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Lothian Research Ethics Committee 2 on the 22nd May 2007 (ref: 07/S1102/12).

Study design
Prospective, double blind randomised controlled trial, single centre study

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
Total knee replacement surgery

Interventions
Two groups of patients will be compared. The only difference in treatment between the two groups will be the use of the PFC Sigma RPF which has a mobile bearing and requires sacrificing of the posterior cruciate ligament and the posterior cruciate ligament retaining PFC Sigma implant which has a fixed bearing.

Follow-up will be one year after surgery when the primary and secondary outcome measures are collected.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Knee excursion during functional activities as measured using electrogoniometry. Primary and secondary outcome measures are collected around one to three weeks before surgery and one year after surgery for both groups.

Secondary outcome measures
1. The passive range of motion of the knee
2. Flexor and extensor strength as measured using a MIE myometer
3. Function as measured by the American Knee Society Score
4. Function, stiffness and pain as measured by the Western Ontario and McMaster Universities (WOMAC) questionnaire
5. Quality of life, using the 36-item short form health survey, version 2 (SF-36 v2)
6. Pain, using the Visual Analogue Score (0 = no pain to 10 = unbearable pain)
7. Walking speed
8. Physical mobility as measured by an activity monitor (activPAL)
9. Canadian Occupational Performance Measure

Primary and secondary outcome measures are collected around one to three weeks before surgery and one year after surgery for both groups.

Overall study start date
01/09/2007

Completion date
01/09/2009

Eligibility

Key inclusion criteria
Ninety suitable men and women (no age limits) with osteoarthritis undergoing a Total Knee Replacement (TKR) at the New Royal Infirmary, Edinburgh who are able to actively flex the knee more than 90 degrees will be recruited from the waiting list of three orthopaedic surgeons. Suitable patients will be identified from medical records and will be living in the Lothian region. All subjects will be medically fit for testing and have no other lower limb impairments.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
90

Key exclusion criteria
1. Inflammatory polyarthritis
2. Disorders of the feet, ankles or hips or spine causing abnormal gait or significant pain
3. Dementia
4. Severe visual impairment
5. Neurological conditions affecting movement
6. Inability to give informed consent
7. Any other disorders of the contra-lateral knee causing abnormal gait or significant pain. Subjects with radiological evidence of osteoarthritis of the contra-lateral knee will be included provided the patient does not report significant pain or restriction in motion of the contra-lateral knee. Similarly patients with total knee arthroplasty of the contra-lateral knee will be included provided the patient does not report significant pain or restriction in motion of the contra-lateral knee.

Date of first enrolment
01/09/2007

Date of final enrolment
01/09/2009

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
School of Health Sciences
Musselburgh
United Kingdom
EH21 6UU

Sponsor information

Organisation
Queen Margaret University (UK)

Sponsor details
c/o Professor Marie Donaghy
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Sponsor type
University/education

Website
http://www.qmu.ac.uk/

ROR
https://ror.org/002g3cb31

Funder(s)

Funder type
Industry

Funder Name
DePuy International Ltd (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?
Results article	results	01/08/2012		Yes	No