

Functional outcome in two different designs of knee replacements

Submission date 19/05/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 24/07/2008	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 09/11/2012	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Marietta van der Linden

Contact details
School of Health Sciences
Queen Margaret University
Queen Margaret University Drive
Musselburgh
United Kingdom
EH21 6UU
+44 (0)131 4740000
mvanderlinden@qmu.ac.uk

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

School of Health Sciences

Queen Margaret University Drive

Musselburgh
Scotland
United Kingdom
EH21 6UU

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