ISRCTN75076749 https://doi.org/10.1186/ISRCTN75076749

A prospective imaging study of cruciate retaining and substituting knee replacement, in osteoarthritis and healthy aging - the PICKLeS study

Submission date
07/10/2011

Recruitment status
No longer recruiting

Registration date
18/11/2011

Overall study status
Completed

Last Edited
22/11/2019

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
In Australia the number of knee replacements implanted increases by 7% each year, reaching 40 700 in 2009. There is an increase in patients aged 55-64 years and this group of people demand a longer life span from the prosthesis and a more active lifestyle. This increases performance demands from the surgery in terms of components, technique and choices, but abnormal knee motion has been linked to poor outcomes and increased wear so it becomes important that the motion for these knee designs is healthy. More than 20 knee designs are available, but well-designed studies of outcomes and knee motion are few. Whether to retain or remove the cruciate ligaments of the knee is a fundamental decision, yet only one RCT of 23 people looks at the motion resulting from this decision.
This study will examine the differences in knee motion between knees with osteoarthritis (OA) and knees of healthy age-matched participants, and two designs of knee replacement, one that retains the posterior cruciate ligament (PCR), and one that substitutes the ligament for a restraint post in the design (PS). The characteristics of knee motion will be related to the various influences of age, osteoarthritis and the decision to keep or remove the ligaments.

Who can participate?
40 participants with osteoarthritic knees awaiting total knee replacement will be recruited. These will be men and women, over 40 years. 40 healthy participants will be chosen by age, gender to match the total knee replacement group. A further 40 healthy participants will be recruited of any gender in groups 20-30 years, 40-50 years, 60-70 years and 80+ years.

What does the study involve?
This study involves a CT image of the knee, and fluoroscopic images while a participant performs some activities, such as rising from a chair. This motion will be built into a 3-dimensional model for analysis. Health outcomes questionnaires, activity measures such as a timed walk, and patient satisfaction will record participants' outcomes.
Each operative participant is matched by age and gender to a healthy participant, and this

participant will also attend for motion study twice, 12 months apart. The age-grouped participants, though attend only once.
Participants in the group awaiting total knee replacement will be randomly allocated to receive either a knee replacement design that retains the posterior cruciate ligament, or one that removes the ligament. These knee replacements are the same in every other way, and will be implanted using the same operative technique. The rehabilitation protocol is also the same for both. Participants will visit for the motion assessment before the operation and twelve months afterward.

What are the possible benefits and risks of participating?
There are no benefits to participating in the study, except that it is interesting to participate in and provides a sense of community participation.
The risks to participation are from the ionising radiation produced by the CT and fluoroscopy. This is about 8mSv, comparable to that received from many diagnostic medical x-ray procedures. The risk is believed to be low and theoretically is equivalent to the risk of being fatality injured in a car accident during accumulating 4000 km of routine travel by car.
There are risks associated with having total knee replacement surgery that are explained by the surgeon when a person consents to surgery. These are infection, blood clots, and many other less common risks. This study does not change the likelihood of these risks.
The total knee replacements are both approved by the TGA for use in Australia. The operation and rehabilitation is performed according to standard procedure. This is not a trial of medication so side effects are not relevant. Risks from the surgery are not altered by this study.

Where is the study run from?
This study will be conducted at the Trauma and Orthopaedic Research Unit at Canberra Hospital in Canberra, Australia.

When is the study starting and how long is it expected to run for?
The study will start in January 2012 and be completed in December 2014.

Who is funding the study?
The study is funded by a research fund of Canberra Hospital and the University of Canberra (Australia).

Who is the main contact?
Prof. Paul Smith
Smithadmin@co.net.au

Contact information

Type(s)
Scientific

Contact name
Prof Paul Smith

Contact details
Clinical Director of Orthopaedics
Trauma and Orthopaedic Research Unit
Canberra Hospital
Building 6, level 1

Garran
Australia
2606

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PICKLeS Protocol v1_24_3_2011

Study information

Scientific Title
A prospective imaging study of cruciate retaining and substituting knee replacement, in osteoarthritis and healthy aging: a randomised controlled trial

Acronym
PICKLeS

Study objectives
Primary hypothesis:
1. A posterior stabilised knee implant design will provide better kinematics outcomes than a posterior cruciate retaining knee implant design for total knee replacement, in terms of tibiofemoral contact pattern and in terms of orthogonal motion of the femur and tibia

Secondary hypotheses:
2. The kinematics of the knee pre-operatively with osteoarthritis determine the post operative kinematics
3. There is a powerful association between knee kinematics and measures of surgical success (KSS), functional outcomes and health related quality of life
4. The characteristics of healthy aging can be determined separately to the characteristics of osteoarthritis on knee kinematics

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. ACT Health Human Research Ethics Committee, ref: ETH 4-11-071
2. ACT Radiation Safety Council approved in May 2011

Study design
Prospective (pre and post op) blinded 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
Knee osteoarthritis, awaiting total knee replacement

Interventions
1. Total knee replacement group:
Participants are randomised to receive one of two knee replacements. A rotating bearing knee, retaining the posterior cruciate ligament, or a posterior stabilised knee that sacrifices the posterior cruciate ligament.

2. Healthy age-matched control group and healthy aging group - observational study only
Knee kinematics is captured by image registration of a pre-operative computerised tomography (CT) scan of the knee to fluoroscopy of the knee while the participant completes various activities. This image registration provides a 3-dimensional model of the knee motion. Post operative knee kinematics is captured by registering the knee prosthesis computer design drawing, to the fluoroscopy images.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Knee kinematics are measured by mapping the tibiofemoral contact pattern, that is defined as the centroid of contact of the femoral condyles on the tibial plateau, while three knee activities:
1. A step up
2. Rising from sitting
3. A squat to flex the knee from 0° to the participants point of full flexion

Secondary outcome measures
1. Knee kinematic analysis by measurement of orthogonal motion in 6 degrees of freedom (3 translations and 3 rotations)
2. Functional tests: Timed Up-and-Go, 6-minute walk test, chair rising x 5 test. Knee Range of Motion
3. Knee Society Score

4. Oxford knee score
5. Patient satisfaction
6. Pain visual analogue measure

Overall study start date
01/01/2012

Completion date
30/12/2014

Eligibility

Key inclusion criteria
1. Total knee replacement group:
1.1. Participant is awaiting total knee replacement
1.2. The surgeon agrees that either a posterior-cruciate-retaining (PCR) or posterior stabilized (PS) knee is equally suitable for this participant
1.3. Participant has osteoarthritis of the knee
1.4. Participant is able to come back for 12 month follow up
1.5. Participant is aged 40 80 years
2. Healthy age-matched control group:
2.1. Participant is age-matched to a participant in total knee replacement (TKR) group
2.2. Participant has no history of injury or osteoarthritis in either knee
2.3. Participant has no pain in either knee
3. Healthy aging group:
3.1. Participant is aged 20-30, 40 50, 60 70, or 80+ years
3.2. Participant has no history of injury or osteoarthritis in either knee
3.3. Participant has no pain in either knee

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
40 participants in each of three groups, totalling 120 participants.

Total final enrolment
25

Key exclusion criteria
1. Total knee replacement group:
1.1. Lateral compartment osteoarthritis only.
1.2. Body mass index (BMI) > 38
1.3. UCLA score of ≤ 2
1.4. Knee flexion < 90°

1.5. Fixed flexion contracture of ≥ 10°
1.6. A psychosocial reason not be able to consent or complete the requirements of the study
1.7. Metastatic disease
1.8. Pathological fracture
1.9. Revision knee replacement
1.10. Poor understanding and is unable to provide informed consent
1.11. Pregnant
2. A healthy age-matched control group participant or a healthy aging group participant:
2.1. Age under 20 years
2.2. History of injury or osteoarthritis in either knee
2.3. Pain in either knee
2.4. Clinically reduced score on oxford knee score
2.5. Clinical examination demonstrates pain, loss of range of motion, injury or osteoarthritis
2.6. X- rays demonstrate injury or ostearthritis

Date of first enrolment
01/01/2012

Date of final enrolment
30/12/2014

Locations

Countries of recruitment
Australia

Study participating centre
Clinical Director of Orthopaedics
Garran
Australia
2606

Sponsor information

Organisation
Canberra Hospital (Australia)

Sponsor details
c/o Mr Lee Martin
Deputy Director ACT Health & General Manager Canberra Hospital
Trauma and Orthopaedic Research Unit
Building 6, Level 1
Yamba Drive
Garran
Australia
2606

Sponsor type
Hospital/treatment centre

Website
http://www.canberrahospital.act.gov.au/

ROR
https://ror.org/04h7nbn38

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Canberra Hospital Private Practice Fund, Canberra (Australia)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date
31/12/2019

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2019	22/11/2019	Yes	No