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Posterior cruciate ligament and total knee arthroplasty: retain, sacrifice or substitute? A prospective, randomised clinical trial

Submission date
11/05/2007

Recruitment status
No longer recruiting

Registration date
12/09/2007

Overall study status
Completed

Last Edited
18/03/2016

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Knee osteoarthritis is a condition where the cartilage inside the knee joint is worn away, leading to the bones rubbing against each other and becoming damaged. In knee replacement surgery, the damaged joint surface is removed and replaced with an implant. The posterior cruciate ligament is one of the four major ligaments of the knee. During knee replacement surgery the posterior cruciate ligament can either be kept in place, removed, or replaced with an implant. The aim of this study is to compare patient outcomes after total knee replacement surgery where the posterior cruciate ligament is retained, sacrificed or replaced.

Who can participate?
Patients aged 18 to 80 with primary osteoarthritis of the knee

What does the study involve?
Participants are randomly allocated to undergo knee replacement surgery where the posterior cruciate ligament is either be kept in place, removed, or replaced with an implant. Participants undergo walking tests and their knee function, osteoarthritis symptoms and quality of life are measured at 2, 5 and 10 years.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Helsinki University Central Hospital (Finland)

When is the study starting and how long is it expected to run for?
April 2006 to December 2018

Who is funding the study?
1. Helsinki University Central Hospital (Finland)
2. Orion-Farmos Research Foundation (Finland)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
TYH7306

Study information

Scientific Title
Posterior cruciate ligament and total knee arthroplasty: retain, sacrifice or substitute? A prospective, randomised clinical trial

Study objectives
To compare clinical, functional and radiological outcome after Total Knee Arthroplasty (TKA) between three different groups:
1. After Cruciate Retaining (CR) TKA and Posterior Cruciate Ligament (PCL) retained
2. After CR TKA and PCL sacrificed
3. After posterior stabilised TKA

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical committee of Surgical Department, Turku University Central Hospital, 02/05/2006, ref: TEKOHeKuTu2006/11032006

Study design

Prospective randomised clinical trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Severe knee osteoarthritis

Interventions
1. Total Knee Arthroplasty (TKA) with Posterior Cruciate Ligament (PCL) retained
2. TKA with PCL excised, but not replaced
3. TKA with PCL excised and replaced with posterior stabilised implant

Follow-up will take place at 10 years.

Intervention Type
Procedure/Surgery

Primary outcome(s)
A 0.8 point (0.5 SD) difference in Total Knee Function Questionnaire and 15 mm difference in Visual Analogue Score (VAS) scale measuring subjective satisfaction, measured at 2, 5 and 10 years.

Key secondary outcome(s))
1. A difference of 15 points in the Western Ontario and McMasters Universities Osteoarthritic Index (WOMAC) questionnaire, converted to a scale of 0 to 100, measured at 2, 5 and 10 years
2. Difference in indicators of functional capacity (20-metre walking test and 3-metre "up and go" test), measured at 2, 5 and 10 years
3. Difference in the observed change in the quality of life, measured at 2, 5 and 10 years
4. Difference in the Oxford Knee questionnaire, measured at 2, 5 and 10 years

Completion date
31/12/2018

Eligibility

Key inclusion criteria
1. Primary osteoarthritis of the knee, planned to be treated by knee replacement surgery
2. Operation can be performed using condylar knee design
3. Collaterals are intact
4. Mechanical axis is at least one degree in varus
5. Aged 18 to 80 years
6. The patient's mother tongue is Finnish

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Not Specified

Key exclusion criteria
1. Patient has a secondary osteoarthritis of knee
2. The patient has undergone endoprosthetic surgery of the other knee or ankle in the preceding 12 months, or such a procedure is planned for the patient in the next 12 months
3. Simultaneous, one-stage knee arthroplasty
4. The patient has undergone surgery of the other knee, hip or ankle with an unsatisfactory outcome
5. The patient has been diagnosed with or is suspected to have an untreated or recurring malignancy or systemic infection
6. A disease treated with cortisone or immunosuppressive medication
7. The patient's cooperation is impaired for any reason
8. Any systemic disease that impairs the patient's mobility
9. Obesity, Body Mass Index (BMI) greater than 40
10. Female patients in fertile age who are planning to have children during the study
11. The patient has previously undergone an operation of the knee region other than arthroscopy or open menisectomy that extended below the subcutaneous tissue
12. The patient has a secondary knee osteoarthritis
13. Permanent patellar dislocation
14. Extra-articular deformity
15. Mechanical axis more than fifteen degrees on varus, neutral or in valgus

Date of first enrolment
20/04/2006

Date of final enrolment
31/12/2018

Locations

Countries of recruitment
Finland

Study participating centre
Helsinki University Central Hospital
Helsinki
Finland
FIN-0009

Sponsor information

Organisation
Helsinki University Central Hospital (Finland)

ROR
https://ror.org/02e8hzf44

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Helsingin ja Uudenmaan Sairaanhoitopiiri

Alternative Name(s)
Helsinki University Central Hospital, HUS

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Finland

Funder Name
Orion-Farmos Research Foundation (Finland)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration