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Combined unicompartmental knee arthroplasty (UKA) and anterior cruciate ligament (ACLR) study

Submission date
12/07/2016

Recruitment status
No longer recruiting

Registration date
21/07/2016

Overall study status
Completed

Last Edited
22/02/2018

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Osteoarthritis is the most common disease affecting the joint. It can develop in any joint but it most often affects those that carry weight, such as the hips, spine and knees. It is caused by damage in and around the joint that can't be fully repaired. Some of the cartilage (the protective layer covering the bones at the joint that ensures the joint moves smoothly) can become damaged or lost, leading to swelling (inflammation), pain and stiffness. Relatively young and more active patients with osteoarthritis (OA) of the isolated medial femorotibial compartment (that is, arthritis of the cartilage between the thigh bone and the shin bone) together with anterior cruciate ligament (ACL) deficiency (tear of the anterior cruciate ligament of the knee) are difficult to treat. The aim of this study was to explore the early clinical outcomes of combined Oxford unicompartmental knee arthroplasty (partial replacement of the knee joint) and ACL reconstruction (tissue graft replacement if the ligament) for patients with ACL deficiency and isolated OA of the medial compartment.

Who can participate?
Adult patients diagnosed of having isolated medial femorotibial compartment OA and ACL deficiency.

What does the study involve?
All patients are treated by combined Oxford UKA and ACL reconstruction. The outcomes of the surgery is then observed over time. This includes the taking of radiographs before and after surgery to look for structural changes of the knee joint. Range of motion is assessed for each patient after surgery and a number of clinical assessments done. This includes testing how stable the knee jpint is, function of the knee and how much pain each patient experiences. All patients are assessed before surgery and then again after 3, 6, 12 and, finally, 24 months.

What are the possible benefits and risks of participating?
The benefits of participating are that the patients with femorotibial OA and ACL deficiency

could be treated with the combined procedures of UKA and ACLR within one surgery. It costs the patients less money and the patients could get recovery fast and earlier. The possible risks are that the combined procedures may fail and get complications after surgery.

Where is the study run from?
The Affiliated Hospital of Qingdao University (China)

When is the study starting and how long is it expected to run for?
January 2008 to January 2014

Who is funding the study?
The Affiliated Hospital of Qingdao University (China)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
AHQDU267718-6

Study information

Scientific Title

Combined unicompartmental knee arthroplasty and anterior cruciate ligament reconstruction in knees with osteoarthritis and deficient anterior cruciate ligament

Study objectives
Relatively young and more active patients with osteoarthritis (OA) of the isolated medial femorotibial compartment in conjunction with anterior cruciate ligament (ACL) deficiency are difficult to treat. The aim of this study was to explore the early clinical outcomes of combined Oxford unicompartmental knee arthroplasty (UKA) and ACL reconstruction for patients presenting ACL deficiency and isolated OA of the medial compartment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Affiliated Hospital of Qingdao University Ethics Committee, 08/10/2007, ref: AHQDU267718-6,

Study design
Observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Unicompartmental knee arthroplasty and anterior cruciate ligament reconstruction

Interventions
All patients were treated by combined Oxford UKA (partial knee replacement) and ACL (anterior cruciate ligament) reconstruction. Plain radiographs in the antero-posterior and lateral view and long-leg standing radiographs were routinely performed prior to and after surgery. Stress radiographs in valgus were additionally available in order to verify the well-preserved lateral compartment. The varus deformity of the knee prior to surgery and the valgus degree after surgery, the posterior slope of the tibial component and the range of motion (ROM) of the knee after surgery were measured and recorded.

Clinical evaluations include Oxford Knee Score (OKS), Knee Society Score (KSS-clinical score; KSS-function score) and Tegner activity score. Follow-up (FU) was done at 1, 3, 6, 12 months after operations and each 1 year thereafter.

Intervention Type

Primary outcome measure
1. Patient assessment of levels of, and change in, pain and function of the knee, using the Oxford Knee Score (OKS)
2. Clinical profile (pain intensity, range of motion and stability in the anteroposterior and mediolateral planes, flexion deformities, contractures and poor alignment.), using KSS-clinical score and KSS-function score
3. Activity levels for daily living, using the Tegner activity score
4. Radiological assessment

Measured before surgery, and then 3, 6, 12 and 24 months after surgery

Secondary outcome measures
Post-operative range of movement, assessed using the KT-2000 arthrometer test, measured before surgery and then 3, 6, 12 and 24 months after surgery

Overall study start date
01/01/2008

Completion date
01/01/2014

Eligibility

Key inclusion criteria
Patients with isolated medial femorotibial compartment OA secondary to ACL deficiency and primary isolated medial femorotibial OA with acute ACL injury.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
At least 25

Key exclusion criteria
1. Severe knee OA apart from the femorotibial compartment
2. Multiple ligment injuries

Date of first enrolment
05/01/2008

Date of final enrolment
30/12/2013

Locations

Countries of recruitment
China

Study participating centre
The Affiliated Hospital of Qingdao University
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Sponsor information

Organisation
The Affiliated Hospital of Qingdao University

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Sponsor type
Other

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https://ror.org/026e9yy16

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
The Affiliated Hospital of Qingdao University

Results and Publications

Publication and dissemination plan

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2016		Yes	No