

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

<b>Submission date</b> 12/07/2016	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 21/07/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 22/02/2018	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> 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 joint 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?

Dr Shaoqi Tian

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## Contact information

**Type(s)**

Scientific

**Contact name**

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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 ligament 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**

No.1677 Wutaishan Road, Huangdao District

Qingdao

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266000

# Sponsor information

## Organisation

The Affiliated Hospital of Qingdao University

## Sponsor details

No. 16 Jiangsu Road

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None

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## Sponsor type

Other

## Website

<http://qyfy.cn/>

## ROR

<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?
<a href="#">Results article</a>	results	01/12/2016		Yes	No