

# Ligaments preservation in total knee arthroplasty

<b>Submission date</b> 11/04/2023	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 13/04/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 13/04/2023	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Total knee arthroplasty was introduced about 30 years ago with the aim to replace the affected knee that is causing severe disability, loss of function and walking limitation. Total knee arthroplasty is considered the most effective treatment for severe knee osteoarthritis and most patients undergoing total knee arthroplasty declare themselves satisfied with the surgery. However, 15-20% of patients report some pain and/or limitation after the operation. It has been proposed that, at least in some cases, the unsatisfactory results may be related to an incorrect ligament balancing of the knee which may cause abnormal stiffness or laxity of the joint during daily activities. In this regard, recent investigations have shown that during total knee arthroplasty, the posterior cruciate ligament (PCL) may be inadvertently cut with potential consequences on the clinical outcome including pain during stair climbing or other physical activities. To explore a possible alternative to reduce the risk of posterior cruciate ligament division during total knee arthroplasty, the aim of this study is to investigate whether a new technique to preserve the posterior cruciate ligament is more effective than the currently used techniques.

### Who can participate?

Patients with knee osteoarthritis scheduled for total knee replacement

### What does the study involve?

Participants are randomly allocated to one of two groups. In group 1 the tibial cut is performed using a double tibial cut, and in group 2 and group 3, the bone island and en bloc resection techniques are used, respectively. PCL integrity and femoral rollback are assessed at the end of surgery.

### What are the possible benefits and risks of participating?

Possible benefits include a better range of motion of the knee after surgery. Risks for participants have not been identified.

### Where is the study run from?

University La Sapienza (Italy)

When is the study starting and how long is it expected to run for?  
February 2017 to October 2021

Who is funding the study?  
University La Sapienza (Italy)

Who is the main contact?  
Prof. Gianluca Cinotti, gianluca.cinotti@uniroma1.it

## Contact information

### Type(s)

Principal investigator

### Contact name

Prof Gianluca Cinotti

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### Protocol serial number

No. 4432, protocol 376/17

## Study information

### Scientific Title

Higher rates of fully preserved posterior cruciate ligament in total knee arthroplasty using a double tibial cut: a prospective randomized controlled trial

### Study objectives

In tibial cutting during total knee arthroplasty, the double-cut technique could avoid posterior cruciate ligament (PCL) transection more consistently than the currently used techniques

### Ethics approval required

Old ethics approval format

## **Ethics approval(s)**

Approved 02/05/2017, Comitato Etico Universita' La Sapienza – Azienda Policlinico Umberto I (Viale Del Policlinico 155, 00161, Rome, Italy; +39 (0)649979822; Comitato. etico@policlinicoumberto1.it), ref: 4432, protocol 376/17

## **Study design**

Randomized prospective trial

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Knee osteoarthritis

## **Interventions**

Patients undergoing cruciate retaining (CR) total knee arthroplasty (TKA) were recruited. A statistical calculator (EpiCalc2000 for Microsoft Windows, version 1.02) was used for the randomization process to generate a code that equally assigned each patient to one of the three groups of treatment, based on age, sex and priority for TKA. In 25 patients (group 1) the tibial cut was performed using a double tibial cut; in 25 (group 2) and 25 (group 3) patients, the bone island and en bloc resection techniques were performed, respectively. PCL integrity and femoral rollback were assessed at the end of surgery. The Oxford Knee Score (OKS), Western Ontario and McMaster University (WOMAC) score and range of motion were assessed postoperatively.

## **Intervention Type**

Procedure/Surgery

## **Primary outcome(s)**

1. The degree of femoral rollback (or posterior translation of femoral condyles on tibial plateaus during the flexion of the knee) on sagittal view of the knee. To avoid any influence of different radiographic magnifications, the femoral rollback was expressed as a percentage (of posterior femoral translation in millimeters with respect of the length in millimeters of the tibial plateau). Measured on radiographic images taken in the operative room at the end of surgery.
2. The knee range of motion measured with a digitalized goniometer in degrees (of knee flexion) at the 2-years follow-up

## **Key secondary outcome(s)**

Assessed before surgery and 3, 6, 12 and 24 months postoperatively:

1. Degree of disability measured using the Oxford Knee Score
2. Pain, stiffness and function measured using the Western Ontario and McMaster University (WOMAC) scale

## **Completion date**

30/10/2021

## **Eligibility**

**Key inclusion criteria**

1. Patients scheduled for primary TKA between June 2017 and June 2019
2. Primary or secondary knee osteoarthritis in which a cruciate retaining total knee arthroplasty was indicated

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Senior

**Sex**

All

**Total final enrolment**

75

**Key exclusion criteria**

1. Previous knee surgeries for degenerative or traumatic conditions
2. Varus-valgus deformity greater than 15°
3. Bone defects or severe flexion contractures requiring a posterior stabilized (PS) implant
4. Patients unwilling to attend clinical follow-ups on a regular basis

**Date of first enrolment**

01/06/2017

**Date of final enrolment**

30/06/2019

**Locations****Countries of recruitment**

Italy

**Study participating centre****Sapienza University of Rome**

Orthopaedic Clinic, Department of Anatomical, Histological, Forensic Medicine and Orthopedic Sciences

Piazzale Aldo Moro 5

Rome

Italy

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**Sponsor information**

**Organisation**

Sapienza University of Rome

**ROR**

<https://ror.org/02be6w209>

**Funder(s)****Funder type**

University/education

**Funder Name**

Sapienza Università di Roma

**Alternative Name(s)**

Sapienza University of Rome, Università degli Studi di Roma "La Sapienza", Sapienza-Università di Roma, Sapienza, Uniroma1

**Funding Body Type**

Government organisation

**Funding Body Subtype**

Universities (academic only)

**Location**

Italy

**Results and Publications****Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study are/will be available upon request ([gianluca.cinotti@uniroma1.it](mailto:gianluca.cinotti@uniroma1.it))

The type of data that will be shared: data in Excel format regarding the results of the study

Dates of availability: immediate

Whether consent from participants was required and obtained: Consent to participate was obtained from all patients

Comments on data anonymization: patients results were reported using a patient code to avoid any possible identification of the patient during the analysis of data

**IPD sharing plan summary**

Available on request