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Ligaments preservation in total knee arthroplasty

Submission date
11/04/2023

Recruitment status
No longer recruiting

Registration date
13/04/2023

Overall study status
Completed

Last Edited
13/04/2023

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
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

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Additional identifiers

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

Primary study design
Interventional

Study design
Randomized prospective trial

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
00185

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)
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