

Ligaments preservation in total knee arthroplasty

Submission date 11/04/2023	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 13/04/2023	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 13/04/2023	Condition category 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

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a participant information sheet

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 measure

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

Secondary outcome measures

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

Overall study start date

01/02/2017

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

Age group

Senior

Sex

Both

Target number of participants

88

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

Sponsor details

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Sponsor type

University/education

Website

<http://www.uniroma1.it/>

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

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

01/06/2023

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