ISRCTN10096716 https://doi.org/10.1186/ISRCTN10096716

Metaphyseal-fitting femoral stems in primary total hip arthroplasty: randomized-prospective comparative outcome study of two different short stems with biomechanical testing and finite element analysis

Submission date
03/04/2018

Recruitment status
No longer recruiting

Registration date
08/05/2018

Overall study status
Completed

Last Edited
19/05/2021

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Total hip arthroplasty (THA) for the treatment of advanced hip osteoarthritis is considered as one of the most successful surgical procedures of the last century, aiming to relieve pain and improve the function of the hip joint. Because of the increased need for better quality of life, THA is increasingly being performed in patients who are younger and more active, thus raising the number of revisions as well. This emphasizes the importance of increasing the longevity of implants and using conservative options that preserve as much bone stock as possible to ease subsequent revision surgery. In an effort to address some of these issues, during the last decades total hip replacement has shown a progressive evolution toward principles of bone and soft tissue sparing surgery. Regarding hip implants, different stem designs have been developed as an alternative to conventional stems, and there is a renewed interest in short uncemented femoral implants. These short stems have been designed in a way to better fit in the proximal femur (thigh bone) and thus behave more similarly to the natural bone. The clinical impact of these innovations would be a more accelerated rehabilitation program, improved long-lasting functional outcome and preservation of bone stock for future revisions. Many manufacturers have designed short-stem implants using different designs to test these theoretical benefits. The aim of this study is to compare the properties and clinical performance of two different short femoral stems used in primary total hip arthroplasty: the TRI-LOCK Bone Preservation Stem (DePuy Orthopaedics Inc. Warsaw, USA) and the Minima S Femoral Stem (Lima corporate Villanova di San Daniele, Italy).

Who can participate?
Patients aged 50-80 undergoing planned total hip replacement for osteoarthritis

What does the study involve?
Participants are randomly allocated to one of two groups: the TRI-LOCK Bone Preservation Stem

group or the Minima S Monolithic Femoral Stem group. The same senior surgeon performs all the arthroplasties with a standard technique. All patients in both groups undergo the same physiotherapy after surgery under the supervision of a certified physical therapist. Patients who manage to complete inpatient physical therapy for independent full weight bearing are discharged from further therapy but those with less compliance continue further rehabilitation. Hip-related complications (fractures, dislocation, wound infection, loosening and revision surgery) are measured for up to 2 years after surgery.

What are the possible benefits and risks of participating?
Participants will not benefit from taking part in this study, but the knowledge gained will help other patients suffering from hip osteoarthritis by finding the best way to treat those who need total hip replacement in the future. Both stems are available for routine use, and as such there are no additional risks in taking part in this study beyond those of having routine total hip replacement surgery.

Where is the study run from?
University Hospital of Patras (Greece)

When is the study starting and how long is it expected to run for?
January 2016 to January 2019

Who is funding the study?
LimaCorporate S.p.A. (Italy)

Who is the main contact?
Dr Irini Tatani

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title
Biomechanical testing, finite element analysis and randomized prospective comparative clinical study of two different metaphyseal-fitting (short) femoral stems in primary total hip arthroplasty

Study objectives
The aim is to conduct a comprehensive assessment, by means of a comparative clinical study as well as biomechanical testing and finite element analysis, of two different short femoral stems, which are theoretically classified in the same main category, as cervico-metaphyseal-diaphyseal short stems. For this reason, the trialists decided to compare a current day short stem, such as the Minima S, for which clinical performance data are lacking with an older generation short stem design, the Trilock BPS with an established performance record in short to midterm follow-up. They hypothesize that even these subtle variations in geometric design between these two stems, may create different loading characteristics and thus dissimilar biomechanical behaviors, which in turn could have an influence on their clinical performance. Consequently, if this scenario is finally confirmed, the conclusions of the present study could not be extrapolated to all short stems even if they belong to the same category.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics committee of the University Hospital of Patras, 22/04/2016, approval number: 36/ 02-03-2016

Study design
Prospective randomized controlled 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 patient information sheet

Health condition(s) or problem(s) studied
Hip osteoarthritis

Interventions
All patients will receive the type of implant to which they have been randomly allocated and thus two groups of patients will be created: group A: Tri-Lock Bone Preservation Stem group and group B: Minima S Monolithic Femoral Stem implantation group. We will use stratified block randomization consisting of a random sequence of blocks of 10 consecutive surgical procedures each.

The same senior surgeon will perform all the arthroplasties with a standardized operative technique through a mini-posterior approach. The femur will be prepared in a broach-only fashion and then the prosthesis will be impacted until a tight metaphyseal fit is achieved. Acetabulum will be prepared in a standardized fashion according to manufacturer's manual with the intention of using larger femoral heads (28-32 mm). Ceramic or polyethylene inserts and ceramic or metallic heads in respect will be used according to surgeon's preference and patients age. All patients in both groups will undergo the same postoperative physiotherapy protocol, which consists of gradual progression from up-to-chair tolerance to ambulation and stair climbing under the supervision of a certified physical therapist. Patients who manage to complete inpatient physical therapy for independent full weight bearing would be discharged from further therapy but those with less compliance will continue further rehabilitation.

Intervention Type
Device

Primary outcome measure
1. The incidence of all hip-related complications up to 2 years after surgery. Hip-related complications are defined as intra- and postoperative fractures, dislocation, wound infection, early or late loosening and revision surgery of any implant for any reason
2. Patient-reported outcome measures, assessed with WOMAC and SF-36 scores at baseline, 3 months, 6 months, 1 year and 2 years

Secondary outcome measures
1. Hip function evaluated with Harris hip score (HHS) at baseline, 3 months, 6 months, 1 year and 2 years
2. Pain measured using the Numeric Pain Rating Scale (NPRS) at baseline, 3 months, 6 months, 1 year and 2 years
3. Patient satisfaction with the outcome at 1 and 2 years, categorized as: overall satisfaction, satisfaction with pain relief, functional improvement to perform daily activities and satisfaction with ability to perform recreational activities. Patients will be classified as very satisfied, somewhat satisfied, somewhat dissatisfied and dissatisfied
4. Functional assessment by motion analysis using an inertial measurement unit (IMU: Free4Act59, 60, Lor An Engineering, Bologna, Italy), based on three different physical performance tests: 1) gait along a 12-m walkway at the patient's self-selected normal speed, 2) 12-m gait in high speed in respect to patient's functional status and 3) up and go test, at 1 and 2 years. The Free4Act sensor is positioned at the dorsal side of the pelvis, centrally between both posterior superior iliac spines. Spatiotemporal gait parameters will be recorded, including: walking speed (m/s), cadence (steps/min) and affected leg step time (s), step length (m), step time irregularity (%), stance and swing phase duration (% of gait cycle)
5. Femoral prosthesis fitting, alignment and stability assessed with detailed radiographic analysis at 3 months, 6 months, 1 year and 2 years

Overall study start date
01/01/2016

Completion date
31/01/2019

Eligibility

Key inclusion criteria
1. Planned total hip replacement for osteoarthritis
2. Unilateral osteoarthritis
3. Patients aged 50-80
4. Diagnosis: primary osteoarthritis, inflammatory arthritis, avascular necrosis, and post-traumatic arthritis
5. Patient willing and able to comply with the study protocol

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
80

Total final enrolment
90

Key exclusion criteria
1. Severe comorbidities affecting the functional outcome (i.e. symptomatic lumbar pathology)
2. Activity-limiting pain in either knee or contralateral hip
3. Patients with poor bone stock or any femoral deformity precluding fit and fill in the metaphysis, such as cases of hip dysplasia and severe valgus or metaphyseal deformity secondary to fracture
4. Planned bilateral procedures within the trial period

Date of first enrolment
15/03/2016

Date of final enrolment
01/01/2017

Locations

Countries of recruitment
Greece

Study participating centre

University Hospital of Patras
Rio
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Sponsor information

Organisation
University of Patras Research Committee (ELKE)

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Sponsor type
University/education

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ROR
https://ror.org/017wvtq80

Funder(s)

Funder type
Industry

Funder Name
LimaCorporate S.p.A.

Results and Publications

Publication and dissemination plan
The study protocol, which includes a statistical analysis plan will be published in a peer-reviewed, open access journal. The results of the study will be presented at national and international orthopaedic meetings. Publication of trial results will be sought through high-impact peer-

reviewed specialty medical or orthopaedic journal with intent to publish around 1 year following the end of the last patient follow-up.

Intention to publish date
31/01/2020

Individual participant data (IPD) sharing plan
The datasets generated and analyzed during the current study will be available upon request from Dr Irini Tatani. All de-identified/anonymized data will become available after the publication of the study results. This is already included in the patient consent form.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	17/06/2019	19/06/2019	Yes	No
Results article		17/05/2021	19/05/2021	Yes	No