ISRCTN12375281 https://doi.org/10.1186/ISRCTN12375281

Effectiveness of shorter femoral stems for hip replacement surgery, testing the biomechanics, using computer simulations, and comparing clinical outcomes between two types of short stems: one with a collar and one without

Submission date
30/04/2024

Recruitment status
Recruiting

Registration date
15/05/2024

Overall study status
Ongoing

Last Edited
04/06/2024

Condition category
Surgery

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Background and study aims
Hip osteoarthritis, a condition increasingly prevalent in the Western world, causes significant suffering for affected individuals. Total hip arthroplasty, a surgical procedure to replace the damaged hip joint, stands as one of the most successful interventions in modern medicine, providing relief from pain for patients. Advances in techniques and technology have widened the accessibility of hip replacement surgery, allowing more patients, even those at younger ages, to benefit from it.
However, this trend has led to a growing need for revising the initial hip replacements as they wear out over time. This presents a challenge that will only become more pronounced in the future. Newer femoral stems, designed to be shorter in length and attach closer to the top of the thigh bone (proximal femoral metaphysis), aim to preserve bone stock and can be implanted without cement, potentially simplifying revision surgeries.
The goal of this research is to compare two types of these short femoral stems: one with a collar and one without. We hypothesize that the collared femoral stem will demonstrate better stability, in terms of both microstability (small-scale movement) and subsidence (sinking into the bone), leading to improved clinical outcomes for patients.

Who can participate?
Patients aged 50 - 80 years requiring a hip replacement.

What does the study involve?
Participants will be randomly allocated to receive the collared femoral stem or the non-collared femoral stem as part of their hip replacement surgery. Follow-up will be for 24 months.

What are the possible benefits and risks of participating?
Added benefits for the patient would be the close monitoring with the treating physician before

and for 2 years after the surgery. Follow-up clinical scores will give the opportunity to the patient to discuss the problems they are facing and find solutions with their physician. Gait analysis will help investigate possible functional deficits.
No added risks for the patient are associated with the current study. The only drawbacks are the additional transports for the patient in order to perform the follow-ups, at the benefit of close physician monitoring.

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

When is the study starting and how long is it expected to run for?
September 2023 to January 2030

Who is funding the study?
University General Hospital of Patras (Greece)

Who is the main contact?
Dr Vasileios Giannatos, vasileiosgiannatos@outlook.com

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Vasileios Giannatos

ORCID ID
https://orcid.org/0000-0002-8599-9604

Contact details
Leykosias 48
Patras
Greece
26441
+30 6945608508
vasileiosgiannatos@outlook.com

Type(s)
Scientific

Contact name
Prof Andreas Panagopoulos

Contact details
Leykosias 48
Patras
Greece
26441
-
andpan21@gmail.com

Type(s)
Scientific

Contact name
Prof Irini Tatani

Contact details
Leykosias 48
Patras
Greece
26441
-
irinitatani@gmail.com

Additional identifiers

Protocol serial number
26646

Study information

Scientific Title
Short metaphyseal-fitting femoral stems in primary total hip arthroplasty: biomechanical testing, finite element analysis and randomized-prospective comparative clinical study of a collared and a non-collared short stem

Study objectives
The collared femoral stem will show superior stability in terms of microstability and subsidence and thus better clinical outcomes regarding patient reported outcomes and gait analysis. Regarding the biomechanical study, our hypothesis is that biomechanical testing and finite element analysis will reveal less subsidence for the collared stem.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 18/01/2024, University General Hospital of Patras Ethics Committee (Rion, Patras, 26504, Greece; +30 2610 997245; achaidop@pgnp.gr), ref: 26646

Study design
Randomized prospective study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied

Total hip arthroplasty for hip osteoarthritis

Interventions
Total hip arthroplasty will be performed in patients with hip osteoarthritis and no hip surgery on the other side or hip dysplasia. The two stems compared will be a short-collared stem and a short stem. Participants are randomized using Random.org.

Clinically, our data will be collected prospectively including patient-reported outcomes questionnaires (HOOS, Harris Hip Score, SF12, VAS), nutritional indexes, biochemical studies, clinical tests (Time Up and Go, 6m Walk Test), hand grip test and gait analysis pre- and postoperatively according to the literature. As far as the radiological results are concerned, a standard anteroposterior pelvis x-ray will be performed pre-operatively and at 3, 6, 12 and 24 months postoperatively, as well as a CT scan preoperatively. Regarding the biomechanical part, a finite element analysis model will be developed and the behavior of the two stems implanted will be modeled. A biomechanical experiment will be set utilizing a loading device to load composite implanted Sawbones under normal circumstances. Inductive miniature displacement transducers and digital image correlation will be used to measure subsidence and stress shielding accordingly. The data from the biomechanical experiment will be used to verify the finitel element analysis model. The verified model will be used to study the behaviour of the two stems regarding the stems' subsidence and strain distribution (stress shielding). An interdisciplinary team of statisticians and clinicians will discuss and correlate the results of the biomechanical and clinical study.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Patient-reported outcomes reported preoperatively and at 3, 6, 12 and 24 months using:
1.1. Hip pain and function measured using Forgoten Joint Score 12 (FJS-12)
1.2. Hip pain and function measured using Hip Disability and Osteoarthritis Outcome Score (HOOS)
1.3. Hip pain and function measured using Harris Hip Score (HHS)
1.4. Pain measured using Visual Analogue Scale (VAS)
2. Quality of life measured using Western Ontario and McMaster Universities Arthritis Index (WOMAC) and 12-Item Short Form Health Survey (SF-12) preoperatively and at 3, 6, 12 and 24 months
3. Stem subsidence measured using anteroposterior pelvis x-ray at 1, 3, 6 and 12 months

Key secondary outcome(s))
1. Gait analysis using VICON 2.4 preoperatively and at 1 and 6 months postoperatively
2. Handgrip strength measured using a Jamar Hydraulic Hand Dynamometer at 3 max repetitions and capturing the best effort preoperatively

Completion date
01/01/2030

Eligibility

Key inclusion criteria
1. Age 50 - 80 years old
2. Primary hip osteoarthritis

3. Inflammatory hip arthritis
4. Hip avascular necrosis
5. Post-traumatic arthritis

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
50 years

Upper age limit
80 years

Sex
All

Key exclusion criteria
1. Inability to participate
2. Hip anatomy that inhibits short stem fitting (Dorr C etc)
3. Active or recent infection
4. BMI >45 kg/m²
5. History of hip surgery
6. Commorbidities that would influence the final outcome (e.g. ankylosing spondylitis, neuromuscular diseases)

Date of first enrolment
20/01/2024

Date of final enrolment
01/01/2028

Locations

Countries of recruitment
Greece

Study participating centre
University General Hospital of Patras
Rion
Patras
Greece
26504

Sponsor information

Organisation
General University Hospital of Patras

ROR
https://ror.org/03c3d1v10

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University General Hospital of Patras

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Vasileios Giannatos (vasileiosgiannatos@outlook.com)

IPD sharing plan summary
Available on request