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Comparing two ways of positioning knee replacement implants and how they affect recovery, movement, and patient satisfaction after knee replacement surgery

Submission date
26/04/2026

Recruitment status
Recruiting

Registration date
27/06/2026

Overall study status
Ongoing

Last Edited
15/06/2026

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Total knee replacement is a common operation used to treat severe knee arthritis. It usually reduces pain and helps people move more easily. However, some people are not fully satisfied after surgery and feel that their new knee does not move as naturally as they expected. Surgeons currently use different methods to position the knee replacement during surgery. This study aims to compare two of these methods to see how they affect pain, movement, daily function, and how satisfied patients feel after surgery. The overall goal is to find out whether one approach leads to better outcomes for patients.

Who can participate?
Adults aged 60–80 years with severe knee osteoarthritis who are scheduled to have a total knee replacement may be able to take part. Participants must not have had previous knee surgery and must be able and willing to attend follow-up visits for up to 2 years after their operation. People with certain medical conditions, such as inflammatory joint disease or major nerve or muscle problems affecting walking, cannot take part.

What does the study involve?
Participants will receive a standard total knee replacement as part of their normal clinical care. The difference between groups is how the surgeon positions the knee implant. One group will have the knee aligned using a traditional method that follows standard measurements, while the other group will have the knee aligned to better match their natural knee shape. After surgery, participants will attend follow-up appointments at 6 months, 12 months, and 24 months. At these visits, they will be asked to complete questionnaires about pain, knee function, quality of life, and satisfaction. X-rays will also be taken to assess knee alignment, and the research team will review medical records for any complications.

What are the possible benefits and risks of participating?
Participants may benefit from close follow-up after surgery and from contributing to research

that could improve knee replacement outcomes in the future. However, taking part may not directly improve their own surgical result. The risks are the same as those linked to routine knee replacement surgery and standard follow-up care, including exposure to X-rays and the possibility of surgical complications. No additional major risks are expected from participating in the study.

Where is the study run from?
The study is run from the General University Hospital of Patras in Greece.

When is the study starting and how long is it expected to run for?
The study began recruiting participants in January 2025. Recruitment is expected to finish in January 2028, with follow-up continuing until January 2029.

Who is funding the study?
The study is investigator initiated and funded.

Who is the main contact?
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Contact information

Type(s)
Principal investigator, Public, Scientific

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Study information

Scientific Title
A case-control study of clinical outcomes, functional performance, and patient satisfaction in kinematically aligned vs. mechanically aligned total knee arthroplasty using medial pivot implants

Study objectives
1. Comparison of pre-operative and postoperative radiological image using the Coronal Plane Alignment of the Knee (CPAK) classification.
2. Patient reported outcomes that include pain, satisfaction rate and quality of life.

3. Comparison of Functional Performance: Range of Motion (ROM), results between the two groups.
4. Postoperative complications: implant wear, implant malalignment, revision rates.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 08/07/2025, Research and Ethics Committee of the University General Hospital of Patras (General University Hospital of Patras, Rio, Patras, 26504, Greece; +30 261 360 3000-3554; kefiap@pgnp.gr), ref: 283/8-7-2025

Primary study design
Observational

Secondary study design
Case-control study

Study type(s)

Health condition(s) or problem(s) studied
Outcomes of kinematic alignment versus mechanical alignment technique in patients undergoing Total Knee Arthroplasty, using medial pivot implants

Interventions
The current study is a case–control study will compare outcomes between kinematically aligned (KA) and mechanically aligned (MA) total knee arthroplasty using medial pivot implants. Patients with end-stage knee osteoarthritis meeting eligibility criteria will be recruited and randomized into two groups. The surgical technique will be roughly the same differing only in the alignment of the limb.
Baseline clinical and radiological data will be collected preoperatively, with follow-up assessments at 6, 12, and 24 months. Primary outcomes include patient-reported measures of pain, function, and satisfaction using scoring systems. Secondary outcomes include radiographic alignment, range of motion, and complication rates.
Patients and outcome assessors will be blinded to group allocation. Statistical analysis will compare outcomes between groups, with significance set at $p < 0.05$.
Ethical approval and informed consent will be obtained prior to study initiation.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Pain measured using Visual Analog Scale (VAS) at 6, 12, 24 month assessment

2. Patient recovery measured using Forgotten Joint Score for the Knee (FJS) at 6, 12, 24 month assessment

3. Knee pain, stiffness, and function measured using KOOS JR (knee injury and osteoarthritis outcome score for joint replacement) at 6, 12, 24 month assessment

4. Pain and physical function measured using Oxford Knee Score at 6, 12, 24 month assessment

Key secondary outcome(s)
1. Psychological distress in patients undergoing total knee arthroplasty measured using Short Form Health Survey questionnaire at 12, 24 month assessment

2. Coronal limb alignment and coronal knee alignment measured using Single leg standing long leg radiographs at 12, 24 month assessment

3. Incidence of postoperative complications including surgical complications, implant malalignment, implant wear, and revision surgery measured using Review of clinical records and radiographic assessments at 12, 24 month assessment

Completion date
01/01/2029

Eligibility

Key inclusion criteria
1. Adults between 60-80 years old
2. Patients with end stage (K-L 3,4) primary knee osteoarthritis
3. Indicated for TKA
4. Eager and able to comply with the 2-year study's follow-up

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
60 Years

Upper age limit
80 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Severe valgus or varus deformity (>15°)
2. Previous knee surgery
3. Inflammatory joint disease affecting the knee joint
4. Neuromuscular disorder affecting gait
5. BMI > 40 kg/m²

Date of first enrolment
01/01/2025

Date of final enrolment
01/01/2028

Locations

Countries of recruitment
Greece

Sponsor information

Organisation
General University Hospital of Patras

ROR
https://ror.org/03c3d1v10

Funder(s)

Funder type

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other files	Sample size calculations		27/04/2026	No	No
Participant information sheet	In Greek		27/04/2026	No	Yes
Protocol file			27/04/2026	No	No