

Prospective Functional, Gait, and Outcome Comparison Study of Medial Pivot Versus Single Radius Design for Total Knee Arthroplasty

NCT04814082

Status	RECRUITING
Phase	Not Applicable
Sponsor	LifeBridge Health
Enrollment	100 participants

Key Eligibility Criteria

Inclusion (6)

- Subject is male or non-pregnant female aged between 18 and 75 years of age.
- Subject is willing to provide informed consent to participate in the research study.
- Subject is indicated for a primary total knee arthroplasty (TKA) based on the approved labeling of knee implant, either a medial pivot or single radius design, specifically: MicroPort Evolution Medial-Pivot Knee System, Cruciate Retaining (CS) or Stryker Triathlon Tritanium (CS)
- Subject does not have a history of previous prosthetic replacement device on the operative knee.
- Subject is currently ambulating and does not have a condition on the contralateral limb in the opinion of the investigator that would interfere with the gait laboratory evaluations.

... and 1 more (see full listing online)

Exclusion (5)

- Subject has a Body Mass Index (BMI) ≥ 40
- Subject has a diagnosis of avascular necrosis or inflammatory arthritis.
- Subject has any mental or neuromuscular disorder that would create an unacceptable risk of prosthesis instability, prosthesis fixation failure, or complications in postoperative care.
- Subject is a prisoner
- Subject has any condition, in the opinion of the Investigator that might interfere with the evaluation of the study objectives.

Locations (1 total)

Sinai Hospital of Baltimore, Baltimore, Maryland, United States