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ClinicalTrials.gov ID: NCT06359301

Study Identification

Unique Protocol ID:	H-34
Brief Title:	H-34 DELTA Revision Cup
Official Title:	An Open Label, Observational, Prospective, Longitudinal Cohort Study to Evaluate Safety, Clinical and Radiographic Outcomes of Total Hip Arthroplasty With DELTA Revision Cup
Secondary IDs:	

Study Status

Record Verification:	April 2024
Overall Status:	Recruiting
Study Start:	September 14, 2021 [Actual]
Primary Completion:	March 31, 2026 [Anticipated]
Study Completion:	March 31, 2029 [Anticipated]

Sponsor/Collaborators

Sponsor:	Limacorporate S.p.a
Responsible Party:	Sponsor
Collaborators:	

Oversight

U.S. FDA-regulated Drug:	No
U.S. FDA-regulated Device:	No
U.S. FDA IND/IDE:	No
Human Subjects Review:	Board Status: Approved Approval Number: 104/B/2020 dated 09 Sept. 2020 Board Name: Bioethics Committee of the Medical Center of Postgraduate Education Board Affiliation: Centrum Medycze Ksztalcenia Podyplomowego Phone: 22-56-01-066 Email: Komisja.bioetyczna@cmkp.edu.pl Address: Bioethics Committee of the Medical Center of Postgraduate Education ul. Marymoncka 99/103

01-813 Warsaw

Data Monitoring: No

FDA Regulated Intervention: No

Study Description

Brief Summary: THis study is aimed to provide a clinical and radiographic evaluation of 49 suitable subjects who underwent a total hip arthroplasty with DELTA Revision acetabular cup.

Detailed Description: This is an observational study designed to reflect real life clinical practice as closely as possible. Thus, clinicians are free to choose the method to implant and total hip arthroplasty in accordance with the current local Delta Revision acetabular cup Indication for Use and current clinical practice.

Conditions

Conditions: Hip, Osteoarthritis

Keywords: revision

Study Design

Study Type: Observational

Observational Study Model: Case-Only

Time Perspective: Prospective

Biospecimen Retention: None Retained

Biospecimen Description:

Enrollment: 49 [Anticipated]

Number of Groups/Cohorts: 1

Groups and Interventions

Intervention Details:

Device: DELTA Revision acetabular cup

Total hip arthroplasty

Outcome Measures

Primary Outcome Measure:

1. Harris Hip Score (HHS)
   Overall score from 0 to 100, with 100 being the best outcome

   [Time Frame: From preoperative to 2 years after surgery]

Secondary Outcome Measure:

2. ROM measurement
   Functional changes in ROM measurements from pre-operative (baseline), discharge, 2 months, 6 months, 1 year and 2 years

   [Time Frame: From preoperative to 2 years after surgery]
3. Oxforn Hip Score (OHS)

Overall score from 0 to 48, with 48 being the best outcome

[Time Frame: From preoperative to 2 years after surgery]

4. Survival rate
   Survival rate expressed with Kaplan-Meier estimator at 2 years after surgery

   [Time Frame: 2 years]

5. Radiographic implant evaluation and stability assessment of the DELTA Revision acetabular cup
   The treated hip is analyzed postoperatively based on anteroposterior and lateral x-rays view of the knee to check for radiographic stability and radiographically detectable complications

   [Time Frame: From preoperative to 2 years after surgery]

6. Incidence, type and severity of all the Adverse Events (AEs), Serious Adverse Events (SAEs), Adverse Device Effects (ADEs), and Serious Adverse Device Effects (SADEs) occurred at each follow-up
   [Time Frame: From preoperative to 2 years after surgery]

Eligibility

Study Population:	The study population consists of 49 consecutive subjects who underwent a THA with the DELTA Revision acetabular cup at the Independent Public Clinical Hospital Prof. Adama Grucy CMKP. Subjects who do not meet all the inclusion criteria or meet any exclusion criteria are excluded from study participation and should be considered as a Screening Failure. Subjects who meet all the inclusion criteria and none of the exclusion criteria and agree to participate in the study signing the Informed Consent Form are enrolled.
Sampling Method:	Probability Sample
Minimum Age:	18 Years
Maximum Age:	
Sex:	All
Gender Based:	No
Accepts Healthy Volunteers:	No
Criteria:	Inclusion Criteria:

- male or female in whom a decision has already been made to perform a total hip arthroplasty with DELTA Revision acetabular cup as per indication for use. The decision to implant DELTA revision acetabular cup must be taken prior to, and independently from the decision to enroll the patient. This decision should be made in accorsance with routine clinical practice at the study site concerned.
- Age ≥ 18 years old
- All patients mist give written informed consent approved by the study site's Institutinal Review Board (IRB)/Ethical Committee (EC)
- Patient is able to comply with the protocol

Exclusion Criteria:

- Adult patients with any DELTA Revision acetabular cup contraindication for use as reported in the current local instruction for use.
- For female patiens, current pregnancy and/or lactation or planning a pregnancy

Contacts/Locations

Central Contact Person:	Federica Azzimonti

Telephone: +39 377 5450940
Email: federica.azzimonti@limacorporate.com

Central Contact Backup:

Study Officials: Jerzy Bialecki
Study Principal Investigator
Samodzielny Publiczny Szpital Kliniczny im. Prof. Adama Grucy CMKP

Locations: **Poland**
Samodzielny Publiczny Szpital Kliniczny im. Prof. Adama Grucy CMKP
[Recruiting]
Otwock, Poland, 05-400
Contact: Jerzy Bialecki

IPDSharing

Plan to Share IPD: No

References

Citations:

Links:

Available IPD/Information: