H-29 and H-34 clinical studies

Clinical Research Department

26 April 2023

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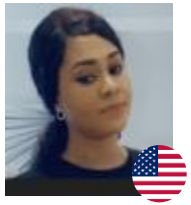

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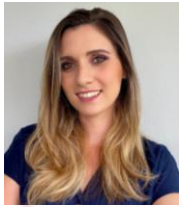

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Jr CRA

H-34 study overview

- **Study title**: An open label, observational, prospective, longitudinal cohort study to evaluate safety, clinical and radiographic outcomes of total hip arthroplasty with DELTA Revision acetabular cup
- **Study design**: Post-market, open label, observational, prospective, longitudinal cohort
- **Study device**: CE marked DELTA Revision acetabular cup
- **Sample size**: 49 patients
- **Time points**: preoperative, intraoperative, at discharge, 2 months, 6 months, 1 year, 2 years, 3 years, 4 years and 5 years after surgery

- **Primary endpoint**: evaluation of Harris Hip Score (HHS) from pre-op to 2 years after surgery
- **Secondary endpoints**:
  - Change in Range of Motion (ROM)
  - Change in Oxford Hip Score (OHS)
  - Implant survivorship
  - Radiographic implant evaluation and stability
  - Incidence, type and severity of AEs, SAE, ADE and SADEs at each time point

- **Site**: Samodzielny Publiczny Szpital Kliniczny im. Prof. Adama Grucy CMKP Księdza Stanisława Konarskiego, 13 - 05-400 Otwock, Poland
- **PI**: Dr. Jerzy Bialecki
- **SubI**: Dr. Julia Macias, Dr. Pawel Bartosz

H-34 Current study status

Study status: enrollment

- 18 patients enrolled
- 17 at discharge
- 14 at 2 months FU
- 11 at 6 months FU
- 6 at 12 months FU

→ ***There are delays in the enrollment rate***

→ ***Target population 49 patients***

Monitoring visits

- **4** Monitoring Visits so far
- Last MV in November 2022
- Monitoring plan: every 2-4 months
- Source Data verification + solve pending queries
- Queries sent by Lima CRA in advance

→ ***5th MV to be scheduled asap***

Next steps

✓ Site contact, low contact in the last months

✓ Speed up enrollment

✓ Schedule 5th MV

H-29 study overview

- **Study title**: A retrospective study evaluating clinical and radiographic early outcomes of Total Hip Arthroplasty with DELTA Multihole TT cup
- **Study design**: Post-marketing, retrospective, observational, monocentric, open-label
- **Study device**: CE marked DELTA Multihole TT acetabular cup
- **Sample size**: 50 patients
- **Time points**: preoperative, intraoperative, at discharge, 2 weeks, 6 weeks, 6 months, 1 year and 2 years after surgery

- **Primary endpoint**: Percentage of HHS score equal or greater than “Good” at 2 years after surgery.
- **Secondary endpoints**:
  - Change in Range of Motion (ROM)
  - Change in VAS Pain score
  - Implant survivorship
  - Radiographic implant evaluation and stability
  - Incidence, type and severity of AEs, SAE, ADE and SADEs at each time point

- **Site**: Samodzielny Publiczny Szpital Kliniczny im. Prof. Adama Grucy CMKP Księdza Stanisława Konarskiego, 13 - 05-400 Otwock, Poland
- **PI**: Dr. Rafal Garlewicz
- **SubI**: N/A

Current study status

Study status: enrollment

- 7 patients enrolled so far
- Planned study duration: 24 months (2 patients/month)
- First Patient In: 6th June 2022

→ ***There are huge delays in the enrollment rate***

→ ***Issues with obtaining Informed Consent***

→ ***No SubI involved***

Monitoring visits

- **1** Monitoring Visit so far on 10th February 2023

→ **We have not received the MV report from CRA**

- Monitoring plan: every 2-4 months
- Source Data verification + solve pending queries
- Queries sent by Lima CRA in advance

→ ***To repeat 1st MV??***

Next steps

- ✓ Contact the site, low contact in the last months
- ✓ Solve ICF issue → contact Ethics Committee and PI, work together to submit the protocol amendment asap
- ✓ Speed up enrollment
- ✓ Repeat 1st MV

Thank You

#emotionofmotion