BAGUERA®C Study #16001

Cervical Arthroplasty using BAGUERA® C: A two-year, prospective, clinical follow-up data registry. Retrospective clinical analysis results

Not FDA approved. Non-US study
Region: Europe
Status: Completed

Pilot study for registration in various countries

Primary Objectives:

- **Safety Evaluation:**
  Evaluation at the end of 2 years post-operative follow-up of the safety of the BAGUERA®C cervical disc prosthesis by analyzing all adverse events reported during the observation period, whether anticipated or unanticipated, related or not to the use of the device.

- **Effectiveness Evaluation:**
  An **overall success rate** was defined as a composite primary endpoint, based on individual overall success evaluated for each subject at 24 months post-operative, based on five parameters taken from clinical and safety evaluation:
  1. *Functional improvement* of 20% at 24 months post-operative, compared to the pre-operative status, evaluated by the Neck Disability Index (NDI).
  2. *Neurological improvement*: conservation of or improvement in three main components of the neurological status: *motor functions, reflexes, sensibility*.
  3. *Neck and Arm Pain*: pain relief of 20% at 24 months post-operative, compared to the pre-operative status, evaluated by VAS scores.
  4. *Improvement in Health-related Quality of Life* of 15% at 24 months post-operative, compared to the pre-operative status, assessed using the Short-Form-36 questionnaire (SF-36 scores)
  5. *No subsequent surgery*.

Indication - condition: Symptomatic cervical degenerative disc disease one or two levels from C3 to C7

Study type: Observational, prospective data collection (registry), retrospective analysis, multicenter cohort study

Patients enrolled: 118

Primary outcomes:

- NDI scores
- Adverse events:
  - Duration (starts and end dates),
  - Seriousness, Intensity, Severity, Anticipated/Unanticipated
  - Relationship to the implant (suspected/not suspected),
  - Re-interventions, Revisions,
  - Relationship to the surgery (suspected/not suspected),
  - Removals or supplemental fixation.
- Neck and Arm Pain by Visual Analogic Scale (VAS)
- Neurological status: motor functions, reflexes, sensibility
- SF-36 scores