TRYPTIK®CA Study #32001

Spinal degenerative discopathy treated by decompression and anterior arthrodesis with intersomatic Poly-Ether-Ether-Ketone anatomical cervical cage TRYPTIK®CA. Evaluation of safety and effectiveness

Investigator Initiated Study
FDA approved for this indication
Region: France
Status: Completed

Post CE-Marking Follow-up Study submitted to HAS (FR)

Primary Objectives:
- Safety evaluation of TRYPTIK®CA, poly-ether-ether-ketone intersomatic cervical anatomic cage, based on all events observed (controls, investigations, hospitalizations, interventions) during up to 31 months follow-up after arthrodesis
- Overall performance of TRYPTIK®CA, evaluated at the end of follow-up period, as a composite primary endpoint, based on data at last visit:
  - Incidence and seriousness of implant related complications
  - Absence of neck and arm pain
  - Absence of neurologic disorders (sensitive and/or motor)
  - Fusion status
  - Patient satisfaction
  - Global prognostic

Secondary objectives:
Early effectiveness assessment, at 3 months post-op for cervical arthrodesis using TRYPTIK®CA:
- Neck and arm pain relief, evaluated by VAS scores
- Functional improvement evaluated by NDI scores
- Quality of Life and Patient satisfaction, evaluated by Odom criteria
- Back to work and normal life
- Radiologic assessment of implant status and fusion process.

Indication - condition: Symptomatic cervical disc degenerative disease

Study type: Observational, cohort, retrospective analysis

Patients enrolled: 31

Primary outcomes:
- Incidence of SAE and AE implant related
- Persistence of neck and/or arm pain
- Absence of neurologic disorders (sensitive and/or motor)
- Fusion status
- Patient satisfaction
- Global prognostic

Secondary outcomes:
- Neck and arm pain (compared to preoperative status)
- Time after surgery for getting back to work
• Changes in physical activities capacity (compared to preoperative status)
• Pain medication (drug's category and frequency)
• Neurologic disorders (motor and/or sensitive)
• Time after surgery for getting back to normal life
• Implant positioning
• Adverse events narratives