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Evaluation of the long-term safety and performance of Baguera® L, a lumbar disc prosthesis used in the treatment of symptomatic lumbar disc disease

Submission date
15/12/2021

Recruitment status
No longer recruiting

Registration date
17/01/2023

Overall study status
Completed

Last Edited
02/06/2023

Condition category
Surgery

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Lower back disc replacement surgery has become a well-established surgical technique in the last 20 years. The disc is replaced with a medical device (prosthesis). Baguera®L is a disc replacement prosthesis for the lower back, it has been on the market since 2008. Clinical studies evaluating Baguera®L demonstrate that overall the reported complication rates were low and the clinical benefit results were excellent. No particular performance issues and/or residual risks were identified. However, there is limited long-term safety and clinical data. Therefore this study is designed to assess the long-term safety and performance of BAGUERA®L.

Who can participate?
The device is used for its intended use, the patients represent the intended population, so any adult patient who received a BAGUERA®L lumbar disk prosthesis

What does the study involve?
Patients need to consent to retrospective data collection from their clinical files from pre-operation to standard follow-up visits as per standard practice (1st FU PO <6 months and/or 2nd FU PO≥6 months) and possibly an additional standard follow-up visit between 4-9 years post-surgery. This additional visit is similar to the previous follow-up visits apart from completing 2 patient self-assessment questionnaires (SF-12 and ODI).

What are the possible benefits and risks of participating?
There are no anticipated benefits for the patient. The information obtained from this study will be used to confirm the safety and efficacy of the BAGUERA® L prosthesis as a part of the Post-Market Surveillance.

There is no significant risk inherent in the study participation. The only additional examination requested out of the standard of practice will be at the French site where the additional follow-up visit is outside of standard clinical practice. This visit and radiological evaluation are part of the annual follow-up standard of practice in Germany

Where is the study run from?
The study is planned in 2 hospitals, one in France and one in Germany.

When is the study starting and how long is it expected to run for?
February 2021 to September 2023

Who is funding the study?
Spineart SA (Switzerland)

Who is the main contact?
clinic@spineart.com

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
P18_CLD004

Study information

Scientific Title
Baguera® L, a lumbar disc prosthesis used in the treatment of symptomatic lumbar disk disease. Long-term evaluation.

Study objectives
The purpose of this study is to collect long-term safety, performance and clinical benefit data following lumbar disc arthroplasty surgery using the BAGUERA®L prosthesis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 21/07/2021, Comité de Protection des Personnes Ile de France VIII (Hôpital Ambroise Paré - 9, avenue Charles de Gaulle, 92100 Boulogne-Billancourt, France; +33 (0)1 49 09 58 14; cppidf8@orange.fr), ref. 21 07 58
2. Approved 01/02/2022, Ethik-Kommission der Bayerischen Landesärztekammer (EK der Bayerischen Landesärztekammer, Mühlbaurstr.16, 81677 München, Germany; +49 (0)89 4147-335; ethikkommission@blaek.de), ref. 21084

Primary study design
Observational

Study design
Retrospective and prospective observational study

Study type(s)
Other

Health condition(s) or problem(s) studied
Surgical treatment of patients suffering from symptomatic lumbar disc disease (SLDD) affecting one vertebral level between L3 and S1

Interventions
Current interventions as of 02/06/2023:

Data collection on consecutive 70 to 100 patients treated with Baguera® L by 2 surgeons between 2013 and 2018.

Data collection will consist of retrospective data from patients' files (pre-operative to post-operational follow-up visits as per standard practice) and prospective data (quality of life - SF-12 questionnaire, pain evaluation - visual analogue scale [VAS] questionnaire and functional capacity - Oswestry disability index (ODI) questionnaire, and radiological exams in flexion and extension) to assess the performance of the device and the mobility of the subject 4-9 years after surgery.

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Previous interventions,:

Data collection on consecutive 70 to 100 patients treated with Baguera® L by 2 surgeons between 2013 and 2017.

Data collection will consist of retrospective data from patients' files (pre-operative to 1-year post-operational follow-up) and prospective data (quality of life - SF-12 questionnaire, pain evaluation - visual analogue scale [VAS] questionnaire and functional capacity - Oswestry disability index (ODI) questionnaire, and radiological exams in flexion and extension) to assess the performance of the device and the mobility of the subject 4-8 years after surgery. Mobility is considered as preserved if the range of motion (ROM) ≥5°.

Intervention Type
Device

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Baguera® L

Primary outcome(s)
Evaluation of the long-term safety associated with the implantation of the BAGUERA®L lumbar disc prosthesis:
Safety measured using the reported incidence and time to resolution of all complications and adverse events related to the medical device and/or procedure, including all surgical revisions peri-and post-operatively up to a least 4 years (4-8 years) post-operative.

Key secondary outcome(s)
Current secondary outcome measures as of 02/06/2023:

Long-term evaluation of the performance of the Baguera®L lumbar disc prosthesis with follow-up at up to at least 4 years (4 to 9 years) post-implantation by measuring the following parameters:
1. Pain measured using the patient's self-reported visual analogue scale (VAS) back and leg, completed pre-operatively, at the 1st PO FU (<6 months) post-operatively and at the last follow-up (4-9 years) post-surgery
2. Pain measured using the Japanese Orthopaedic Association (JOA) questionnaire at the pre-operative visit and at the 1st PO FU (<6 months) and 4-9 years post-operative.
3. Functional capacity assessment measured using the patient's self-reported Oswestry disability index (ODI) questionnaire at the last follow-up (4-9 years) post-operative
4. Quality of life in relation to health and patient satisfaction measured using the patient self-reported SF-12 questionnaire at the last follow-up 4-9 years post-operative
5. Evaluation of the lumbar mobility at the treated level and at L1-S1, by radiological assessment of the Range Of Motion (ROM) based on lateral X-ray images in flexion and extension at the 2nd PO FU (≥6 months) and at the last follow-up (4-9 years) post-operative.
6. Evaluation of disc height at the treated level and at the suprajacent level, measured using radiological assessment based on neutral lateral X-ray images at the preop-operative visit, the 1st PO FU (<6 months), the 2nd PO FU (≥6 months) and the last follow-up (4-9 years) post-operative.
7. Evaluation of the subsidence at the treated level and the listhesis, by radiological assessment based on X-ray images at the pre-operative visit, the 1st PO FU (<6 months), the 2nd PO FU (≥6 months) and the last follow-up (4-9 years) post-operative.
8. Pain medication and clinical and neurological evaluation measured at pre-operative visit, before discharge and at the 1st PO FU (<6 months), the 2nd PO FU (≥6 months) and the last follow-up (4-9 years) post-operative.
9. Retrospective evaluation of the surgical instruments used for implantation of the device

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Previous secondary outcome measures:

Long-term evaluation of the performance of the Baguera®L lumbar disc prosthesis with follow-up at up to at least 4 years (4 to 8 years) post-implantation by measuring the following parameters:
1. Pain measured using the patient's self-reported visual analogue scale (VAS) back and leg,

completed pre-operatively, 6-12 weeks post-operatively and at the last follow-up (4-8 years) post-surgery
2. Pain measured using the Japanese Orthopaedic Association (JOA) questionnaire at the pre-operative visit and at 6-12 weeks, 1 and 4-8 years post-operative
3. Functional capacity assessment measured using the patient's self-reported Oswestry disability index (ODI) questionnaire at the last follow-up (4-8 years) post-operative
4. Quality of life in relation to health and patient satisfaction measured using the patient self-reported SF-12 questionnaire at the last follow-up 4-8 years post-operative
5. Lumbar mobility at the treated level measured using radiological assessment of lateral X-ray images in flexion and extension at 1 year and at the last follow-up (4-8 years) post-operative. Mobility is considered preserved if ROM ≥ 5°
6. Evaluation of disc height at the treated level measured using radiological assessment of X-ray images at 1 year and the last follow-up (4-8 years) post-operative. Disc height is considered preserved if the height (measured at anterior, middle and posterior vertebral endplates) is similar to the height of the superjacent non-pathological level
7. Pain medication and clinical and neurological evaluation measured using the VAS, ODI, SF12 and JOA questionnaires (as per standard practice, if available) with data collected retrospectively from the patients' clinical files from pre-operative until the 1-year postoperative follow-up and during the last prospective visit
8. Retrospective evaluation of the surgical instruments used for implantation of the device in terms of safety and performance measured using device deficiencies and complications (if any) documented in the Complaint Reports at the time of the surgery

Completion date
30/09/2023

Eligibility

Key inclusion criteria
Patients aged between 18 and 65 years, who have received one Baguera® L as per the IFU and who signed an Informed consent or Information letter.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria

1. Contraindications as per IFU
2. Pregnant or breastfeeding women
3. Patients unable to give written consent, e.g. legally incapacitated

Date of first enrolment
15/12/2021

Date of final enrolment
22/11/2022

Locations

Countries of recruitment
France

Germany

Study participating centre
Centre Aquitain du Dos
2 Rue Georges Nègrevergne
Mérignac
France
33700

Study participating centre
Grenzland MVZ Furth im Wald GmbH
Dr.-Adam-Voll-Strasse 1
Furth im Wald
Germany
93437

Sponsor information

Organisation
Spineart (Switzerland)

ROR
https://ror.org/05sz2c652

Funder(s)

Funder type
Industry

Funder Name
Spineart SA

Results and Publications

Individual participant data (IPD) sharing plan
The dataset generated and analysed during the current study will be available upon request from clinic@spineart.com. Consent requested from participants was required and obtained. All data entered in the database are completely anonymized. The sites are responsible for the anonymization of the radiological images required for the study evaluation. There are no known ethical or legal restrictions.

IPD sharing plan summary
Available on request