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Evaluation of outcomes after spinal fusion surgery using a titanium-secured cage

Submission date
20/02/2023

Recruitment status
No longer recruiting

Registration date
09/03/2023

Overall study status
Completed

Last Edited
09/03/2023

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Degenerative Disc Disease (DDD) is a condition where the discs that separate and cushion the vertebrae in the spine break down and lose their ability to absorb shock. This can cause pain, stiffness, and reduced mobility in the back or neck.
Anterior lumbar interbody fusion (ALIF) with cages is a surgical procedure used to treat certain conditions of the lower back, such as degenerative disc disease, herniated discs, or spinal instability. During the procedure, the surgeon makes an incision in the front of the abdomen, and the affected disc is removed from between the vertebrae. A cage made of bone, metal, or plastic is then inserted into the space left by the removed disc. The cage is packed with bone graft material, which over time grows and fuses the adjacent vertebrae together, stabilizing the spine. The use of cages in ALIF procedures has been a well-established technology for several decades and has been found to be effective in treating certain conditions of the lower back. Recently, cages with integrated fixation have been used to make the devices safer and more effective in promoting fusion. SCARLET® AL-T is a device that was introduced in 2019 and is categorized as a stand-alone anterior interbody device with integrated screws. It has been shown that this type of device is effective in treating Degenerative Disk Disease. The purpose of a non-interventional, observational study is to collect real-world evidence on the safety and clinical benefits of SCARLET® AL-T for 24 months after surgery. The goal is to confirm that the SCARLET® AL-T system is safe and effective for long-term clinical benefits and radiographic outcomes after stand-alone anterior lumbar interbody fusion surgery.

Who can participate?
Any adults (at least 18 years old) needing lumbar interbody fusion surgery for DDD who received the SCARLET®AL-T system as intented therapy.

What does the study involve?
The pre-operative data and surgical data will be collected retrospectively, the post-operative data at 3, 6 and 12 months will be collected either retrospectively or prospectively, and the 24-month post-operative data will be collected prospectively.
CT scans will be performed to assess fusion and stability over time as per standard of care.

Patient questionnaires will be completed by patients to collect clinical data and evaluate changes in pain, disability and improvment between baseline and post-operation as per standard of care.

What are the possible benefits and risks of participiating?
As this study is non-interventional and consists of the collection of data following the site standard of care, there is no risk for the patients and no anticipated benefits. Information obtained will be used to confirm the safety and efficacy of the device as part of the Post-Market surveillance.

Where is the study run from?
Spineart SA (Switzerland)

When is the study starting and how long is it expected to run for?
November 2019 to December 2024

Who is funding the study?
Spineart SA (Switzerland), manufacturer of the SCARLET®AL-T system.

Who is the main contact?
clinic@spineart.com

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
P76_CLD001

Study information

Scientific Title
Clinical and radiographic evaluation of the lumbar Scarlet AL-T cage outcomes within 24 months postoperatively

Acronym

SCARLET AL-T study

Study objectives
Clinical and radiographic evaluation of the lumbar Scarlet AL-T cage outcomes

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 27/01/2021, CPP Est IV (1, place de l'Hôpital, 6091 Strasbourg, France; +41 3 88 11 60 03; cpp.est@14chru-strasbourg.fr), ref. SI 20_08_17_37523

Primary study design
Observational

Study design
Observational registry single center study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Surgical treatment of Degenerative Disk Diseases (DDD)

Interventions
The SCARLET®AL-T system may be implanted via an open or a minimally invasive anterior approach. As part of an observational study, the SCARLET®AL-T system should be implanted with an ALIF surgical approach per the site standard of care.

Once the patient agreed to participate, the non-opposition process has been completed, eligibility criteria has been confirmed, the following data are collected retrospectively: preoperative visit (V0), surgery (V1), and discharge (V2).
The screening visit may be combined with the 3-month (V4), 6-month (V5) or 12-month (V6) post-operative follow-up visit. Depending on when the patient was included (at 3-, 6- or 12-month visit), these data are either collected prospectively or retrospectively.
The 24-month (V7) visit is always collected prospectively.

Total duration of follow-up: the patients' participation in the study will last from 12 to 21 months after his 1st visit (3-, 6- or 12- Month post-procedure).
Total duration of observation: from preoperative visit to 24- month so around 25 months (depending when was done the preoperative visit).

Intervention Type
Device

Phase
Phase IV

Drug/device/biological/vaccine name(s)
SCARLET®AL-T system

Primary outcome(s)
Evaluate SCARLET®AL-T system performance by assessing interbody fusion by CT scan at 24 months post-operatively.

Key secondary outcome(s)
1. Assessment of fusion at 3, 6, and 12 months post-operatively by CT-scan.
2. Stability at 3, 6, 12 and 24 months post-operatively by assessing the subsidence, visible vertebrae endplate fracture and device mobility.
3. Safety assessment: Adverse Events. All perioperative and postoperative adverse events will be assessed for relationship to device and procedure, seriousness, incidence and time to resolution or re-operation. Incidence of re-intervention at the treated level will be assessed.
4. Disability and Change in Disability for low back pain. Obtaining improvement in Oswestry Disability Index (ODI) disease-specific questionnaire up to 24 months following the procedure, as compared to patient's baseline. Mean change in score of the ODI from baseline (the preoperative status) to 3-, 6-, 12- and 24-months postoperative values.
5. Pain and Change in Pain (Back and Leg): obtaining improvement in Visual Analogue Scale (VAS) Back and Leg pain scores up to 24 months following the treatment as compared to patient's baseline. Mean change in score of the VAS from baseline (the preoperative status) to 3-, 6-, 12- and 24-months postoperative values.
6. Patient satisfaction at 3-, 6-, 12- and 24-months postoperative based on the PRO (SF-12).
7. Evaluation of Spineart’s instrumentation supporting the surgery, enabling the implanted device to perform according to its intended use, in terms of safety and performance

Completion date
31/12/2024

Eligibility

Key inclusion criteria
1. Age 18 years minimum
2. Treated by interbody fusion with SCARLET®AL-T system
3. Non opposition letter signed

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria

1. Patient lacking capacity to follow postoperative care instructions due to mental state (suffering from dementia and others)
2. Infection
3. Severely damaged bone structures that could prevent stable implantation of the cage
4. Neuromuscular or vascular disorders or illness
5. Inadequate activity
6. Pregnancy
7. Bone tumor in the region of implant
8. Fractures

Date of first enrolment
06/05/2021

Date of final enrolment
13/06/2022

Locations

Countries of recruitment
France

Study participating centre
Clinique du Parc, CCV MONTPELLIER
50 Rue Emile Combes
Castelnau Le Lez
France
34170

Sponsor information

Organisation
Spineart SA

Funder(s)

Funder type
Industry

Funder Name
Spineart SA

Results and Publications

Individual participant data (IPD) sharing plan
For the moment, data-sharing plans are unknown. In the meantime, the datasets generated during and/or analysed during the current study will be available upon request from clinic@spineart.com. Consent requested from participants was required and obtained.

IPD sharing plan summary
Available on request