ISRCTN12002403 https://doi.org/10.1186/ISRCTN12002403

Performance and safety Clinical study on JULIET®TI LL cage in fusion lumbar spinal surgery

Submission date
13/04/2022

Recruitment status
No longer recruiting

Registration date
12/05/2022

Overall study status
Ongoing

Last Edited
19/02/2024

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) in the lumbar spine (lower back) occurs when age-related wear and tear on a spinal disc causes low back pain. Surgery for lumbar DDD is recommended when non-surgical treatment fails. There are different surgical techniques for lumbar fusion. One of them is the lateral approach, called lumbar lateral interbody fusion (LLIF). LLIF is a minimally invasive surgery to treat disc problems causing pain in the low back. In spinal fusion, two or more vertebrae (bones) of the spine are joined to stop painful motion and to decompress pinched nerves. Through a small incision at the side of the waist, the damaged disc is removed and replaced with a spacer. The spacer (also called a cage) restores the height between the bones and relieves pinching of the spinal nerves. The cage becomes a bridge between the two bones and is filled with bone graft to promote fusion. In some cases, the cage is strengthened with a plate and screws on the side or with pedicle screws from the back. This study aims to confirm the performance and safety of the Spineart lateral cage: Juliet Ti LL. The study's findings should help to improve the well-being of future patients with lumbar DDD.

Who can participate?
Patients aged 18 years and over, scheduled for lateral lumbar interbody fusion surgery

What does the study involve?
The surgery and the majority of the follow-up visits/exams are part of routine care. The study lasts 2 years in total, with a preoperative visit, the surgery, and 3-, 6-, 12- and 24-month postoperative visits. Participants also complete online questionnaires during the study period.

What are the possible benefits and risks of participating?
There are no anticipated personal benefits for the patients besides achieving fusion and reducing pain. In addition to the routine procedures, the radiologic exams used for this study include up to two CT scans at 12 and 24 months after surgery. They may be an ionization risk for the additional exams.

Where is the study run from?
Spineart (Switzerland)

When is the study starting and how long is it expected to run for?
March 2021 to November 2024

Who is funding the study?
Spineart (Switzerland)

Who is the main contact?
clinic@spineart.com

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
JULIET Ti LL / P77_CLD001

Study information

Scientific Title
Prospective evaluation of clinical and radiographic outcomes after lumbar lateral interbody fusion surgery using a JULIET® Ti LL interbody fusion cage

Acronym
Juliet Ti LL

Study objectives
The sample size of 71 study participants allows for detection of the primary endpoint of 90% in the target population with 80% power at two-sided 5% significance.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 30/07/2021, CPP Ile de France VII (CHU de Bicètre, 78 rue du Général Leclerc, 94275 le Kremlin Bicètre Cedex, France; +33 (0)1 45 21 28 46; cpp.idf.7-bicetre@wanadoo.fr), ref: 2021-A01537-34
2. Approved 29/03/2022, CEIM - Hospital Universitario Y Politécnico La Fe (Instituto de Investigación Sanitaria La Fe, Torre A – Planta 7ª – Despacho 7.02, Avenida Fernando Abril Martorell, 106, 46026 Valencia, Spain; +34 (0)96 124 66 05; ceic@iislafe.es), ref 520
3. Approved 05/01/2023, Ethik Kommission der Ärztekammer Westfalen-Lippe und der Westfällischen Wilhelms-Universität (Gartenstrasse 201-214, 48147 Münster, Germany; +49 (0) 251 929 2460; ethhik-kommision@aekwl.de), ref: 2022-580-f-S

Study design
Prospective interventional single-arm multicenter study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format

Health condition(s) or problem(s) studied
Patients with symptomatic degenerative lumbar disc diseases (DDD) and spondylosisthesis, functionally disabling discogenic low back pain that does not improve after conservative care

Interventions
The JULIET® Ti LL intervertebral implant is indicated for degenerative disk disease (DDD) and spondylosis causing chronic low back pains resistant to conservative management and when a surgical intervention with fusion technique is needed. Fusion consists of uniting one or more vertebrae of the spine together so that motion no longer occurs between them, eliminating instability. The JULIET® Ti LL interbody devices are to be used with autogenous and/or allogenic bone graft to facilitate fusion.

The approach technique is lateral lumbar interbody fusion (LLIF) which is minimally invasive and involves accessing the disc space via a lateral retroperioneal, transpsoas or pre-psoas corridor. The study duration for the enrollment period is estimated to be 9 months and each patient should be followed up to 24 months postoperatively.

Intervention Type
Device

Phase
Phase IV

Drug/device/biological/vaccine name(s)
JULIET® Ti LL Lateral cage

Primary outcome measure
The interbody fusion performance of JULIET® Ti LL system measured by spine CT scan within 24 months postoperatively

Secondary outcome measures
1. Subsidence assessed with standing neutral lateral x-rays at 3-, 6-, 12- and 24-months postoperative visits
2. Lordosis restoration and sagittal balance assessed with full spine x-ray/teleradiography of the spine at 12- and 24-month postoperative visits
3. Safety assessed using all perioperative and postoperative adverse device effects (ADE) and serious adverse events (SAEs)
4. Pain assessed using Visual Analogue Scale (VAS) Back and Leg pain scores at 3-, 6-, 12- and 24-months postoperative visits
5. Health-related quality of life assessed using the SF-12 health survey at 3-, 6-, 12- and 24-months postoperative visits
6. Low back disability assessed using Oswestry Disability Index (ODI) disease-specific questionnaire at 3-, 6-, 12- and 24-months postoperative visits
7. Patient satisfaction assessed using questionnaire at 3, 6, 12 and 24 months postoperative visits
8. Safety and performance of the instrumentation supporting the surgery assessed using questionnaire at time of surgery

Overall study start date
01/03/2021

Completion date
15/11/2025

Eligibility

Key inclusion criteria
1. Skeletally mature subjects, ≥18 years old
2. Indicated DDD defined as discogenic back pain with degeneration of the disc confirmed radiographically and by patient history
2.1. DDD, or
2.2. DDD with up to grade I Spondylolisthesis, or

2.3. DDD with up to grade I Retrolisthesis
3. Psychosocially, mentally, and physically able to fully comply with the protocol including adhering to follow-up schedule and filling out questionnaires.
4. Written voluntary informed consent signed

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
At least 71 patients

Total final enrolment
74

Key exclusion criteria
1. Mental illness
2. Infection
3. Severely damaged bone structures that could prevent stable implantation of the cage (bone density in SD ≤-2.5)
4. Neuromuscular or vascular disorders or illness
5. Inadequate activity (inability to follow postoperative rehab restriction)
6. Pregnancy
7. Bone tumor in the region of the implant
8. Fractures (same level treated or adjacent level: active, non-consolidated, or old osteoporotic fracture)

Date of first enrolment
18/03/2022

Date of final enrolment
15/11/2023

Locations

Countries of recruitment
France

Germany

Spain

Study participating centre
Centre Francilien Du Dos
7 bis, Rue de la Porte de Buc
Versailles
France
78000

Study participating centre
Centre Est Lyonnais du Dos
Hôpital privé de l'Est Lyonnais (HPEL) - Ramsay Santé
140 Rue André Lwoff
Saint-Priest
France
69800

Study participating centre
Hospital Manises
Traumatología Y Cirugía Ortopédica – Unidad De Raquis. Hospital De Manises
Av. de la Generalitat Valenciana, 50,
Manises, Valencia
Spain
46940

Study participating centre
St. Christophorus Krankenhaus
Am See 1
Werne
Germany
59368

Study participating centre
Clinique Trénel
rue du Dr Trénel
Sainte-Colombe
France
69560

Sponsor information

Organisation
Spineart (Switzerland)

Sponsor details
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Sponsor type
Industry

Website
https://www.spineart.com/

ROR
https://ror.org/05sz2c652

Funder(s)

Funder type
Industry

Funder Name
Spineart SA

Results and Publications

Publication and dissemination plan
Interim analysis and final results are planned.

Intention to publish date
31/12/2026

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date