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Fusion rate after using an Intersomatic JULIET®TI cages in lumbar spinal surgery

Submission date
15/12/2021

Recruitment status
No longer recruiting

Registration date
08/11/2022

Overall study status
Completed

Last Edited
13/12/2024

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:
This study will investigate the performance and safety of the JULIET®TI cage and evaluate the primary stability and the intervertebral fusion status of the lower spine using a SPEC-CT scan, in patients who received fusion surgery (joining two spinal bones, known as vertebrae) on the lower back to treat lumbar Degenerative Disk Disease (DDD), spondylolisthesis, thoracic and lumbar fractures, vertebrate tumors, or pseudarthrosis. The JULIET®TI cage is a type of prosthesis used to maintain height and decompression of the spine following this procedure. SPECT-CT has been demonstrated to provide improved diagnostic accuracy compared to CT-Scan. It will be used in this study to detect early signs of interbody fusion and adjacent levels of bone healing, following treatment with the JULIET®TI cage.

Who can participate?
Any adult patient needing treatment with a fusion system. The device is used for its intended use and patients represent the intended population.

What does the study involve?
The study involves the collection of data of patients who have received treatment with the JULIET®TI cage. Data will be collected before surgery, during the surgery for device and instrument assessment (from the surgeon), immediately after surgery, and after 3, 6, and 12 months. Questionnaires will be used to collect data on quality of life and improvements in pain and functioning. at 6 and 12 months SPEC-CT scan will be used to assess interbody fusion status.

What are the possible benefits and risks participating?
There is no direct benefit to the patient in participating in the study. Nevertheless, the post-operation SPEC-CT exams used as part of the study, compared to standard X-rays or CT scans, could have a more accurate evaluation of bone healing and diagnosis of postoperative complications that may cause pain, allowing physicians to choose targeted therapies and avoid potential unnecessary re-interventions,

There are no additional risks to the patient participating in the study versus normal clinical practice for patients being treated by JULIET Ti. The SPEC-CT vs X-rays/CT Scan and additional radiological exams requested by the protocol will consist of a total of 7,2mSv which is considered as low by the UNSCEAR.

Where is the study run from?
Spineart (Switzerland)

When is the study starting and how long is it expected to run for?
From October 2018 to June 2025. The study started recruitment in 2020, then was put on hold due to public health guidance at the time.

Who is funding the study?
Spineart (Switzerland) the manufacturer of the Juliet Ti cages

Who is the main contact?
clinic@spineart.com

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
P74_CLD001

Study information

Scientific Title
Evaluation by SPECT-CT of early signs of interbody fusion following lumbar arthrodesis using a Titanium porous cage

Acronym
JULIET-TI Observational

Study objectives
Assessment of the performance, clinical benefit and safety of the device up to one year after the surgical implant, in line with MEDDEV and the New Medical Device Regulations (MDR) and used in accordance with its approved labelling.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 06/01/2020, Commission Cantonale d'Ethique de la Recherche (CCER) (rue Adrien-Lachenal 8, 1207 Genève, Suisse; 41 (0) 22 546 51 01; ccer@etat.ge.ch), ref: 2018-02376

Study design
Prospective two-center single-arm post-market observational cohort study

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
arthrodesis of the lumbar spine at one level or at two contiguous levels between L2 and S1 to treat:
1. Degenerative pathologies (recurrent hernia, degenerative spondylolisthesis, symptomatic disc disease)
2. Spondylolisthesis by isthmic lysis
3. Spine deformity (scoliosis, instability)
4. Stenosis

Interventions
The study design follows a prospective methodology. It is an observational PMCF study planned to be conducted in a standard of care setting in 2 sites in Geneva, to observe patients who underwent lumbar arthrodesis (fusion surgery) using the JULIET®-TI cage for 12 months after surgery. Participants will be selected during regular consultations for lumbar pathologies and recruited by the Investigators in accordance with their normal clinical practices and the device IFU.
SPECT-CT will be carried out at 6 and 12 months post-operatively to evaluate the intervertebral fusion status. At one site, a CT scan will be carried out normally done at 6 months, and at the other site, a CT scan is normally done at 12 months.
Safety, performance, and clinical benefit will be assessed up to 12 months post-operatively. The improvement of the patient's disability, pain, and quality of life, as well as early bone metabolic signs, the instrumentation supporting the surgery, and safety will also be evaluated.

Intervention Type
Device

Phase
Phase IV

Drug/device/biological/vaccine name(s)
JULIET®-TI (titanium) cage

Primary outcome(s)
Interbody fusion status will be qualitatively assessed for all evaluable subjects, using SPECT-CT taken at 6 and 12 months post-surgery

Key secondary outcome(s))
1. Safety will be measured using adverse events (AEs), severe adverse events (SAEs), and complications recorded throughout the 12 month study period
2. Performance and clinical benefit:
2.1. Disability measured using the ODI functional assessment score at baseline (pre-operative), 3, 6, and 12 months
2.2. Pain measured using the VAS pain assessment score at baseline (pre-operative), 3, 6, and 12 months
2.3. Quality of life (QoL) measured using the Short form-12 (SF-12) self-assessment questionnaire score at baseline (pre-operative), 3, 6, and 12 months
2.4. Early bone metabolic signs of interbody fusion measured in the adjacent levels to implant by bone scan with SPECT-CT at 6 months
2.5. Primary stability measured using dynamic X-ray by ROM angles between flexion/extension at baseline and
3. Instrumentation support for the following tasks: to prepare the site of implantation, to select the adequate implant, to perform the implantation, to finalize the surgery; will be evaluated in terms of safety and performance using device and instrument assessment by the surgeon during and immediately after the surgery

Completion date
01/06/2025

Eligibility

Key inclusion criteria
1. Skeletally mature patients, aged ≤80 years
2. Treated by interbody fusion with JULIET-TI at 1 or 2 contiguous levels from L2 to S1
3. Symptomatic degenerative disc disease (SDDD), Recurrent herniated disc, Isthmic spondylolisthesis, or Degenerative spondylolisthesis Grade I
4. Non-smokers or recent quitters (for ≥3 months)
5. Treated non-surgically (for ≥6 months)
6. No previous surgery at the level to be treated, or previous surgery at the level to be treated without implantation of any material (i.e. operated for herniated disc or decompression)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Upper age limit
80 years

Sex
All

Key exclusion criteria
1. Previous surgery at the level to be treated with implantation of material (i.e. arthrodesis or arthroplasty)
2. Infection at the index level
3. Burst fracture and/or comminuted fracture of the vertebral body and/or vertebral plate
4. Osteoporosis, poor bone quality, or tumour
3. Current smokers
4. Spondylolisthesis Grade II or higher
6. Known metal sensitivity
7. Mental illness, hyperactivity
8. Neuromuscular and/or vascular disorder or illness
9. Pregnancy (current or planned next in the next 6 months)

Date of first enrolment
22/06/2020

Date of final enrolment
31/01/2024

Locations

Countries of recruitment
Germany

Switzerland

Study participating centre
Hôpital Universitaire de Genève
Rue Gabrielle-Perret-Gentil 4
Geneva
Switzerland
1205

Study participating centre
Clinique Générale de Beaulieu Genève
Chemin Beau-Soleil 12

Geneva
Switzerland
1206

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 datasets generated and/or analysed during the current study will be published as a supplement to the results publication

IPD sharing plan summary
Published as a supplement to the results publication