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Prospective clinical study to evaluate the performance and safety of the TRYPTIK® Ti cage after cervical spinal fusion surgery

Submission date
04/10/2021

Recruitment status
No longer recruiting

Registration date
04/10/2021

Overall study status
Completed

Last Edited
09/12/2024

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
The aim of this study is to confirm the performance and safety of the Tryptik Ti cage in anterior cervical discectomy and fusion (ACDF) surgery for cervical degenerative disc disease (DDD) or spondylosis. An ACDF is a surgery to remove a painful herniated or degenerative disc in the neck. A small cut is made in the front (anterior) of the neck to reach and remove the damaged disc and the disc is replaced with a cage. The cage is inserted to restore the height between the bones and to fuse together the bones above and below the disc. ACDF surgery may be an option if physical therapy or medications fail to relieve neck or arm pain caused by pinched nerves. Patients typically go home the same day.

Who can participate?
Patients aged 18 years and over requiring ACDF with a cage

What does the study involve?
Data will be collected before the surgery and during the surgery for device and instrument assessment from the surgeon's point of view. The visits after surgery are mainly standard, with assessments performed immediately after the surgery, between 6 and 12 weeks and after 6, 12 and 24 months. X-rays and CT scans will be performed. Patient questionnaires will assess pain, disability and quality of life.

What are the possible benefit and risks of participating?
There are no direct benefits to participating in the study. The potential benefits of the cage and ACDF are achieving fusion of the treated level, achieving cervical spine stability, and reducing pain. The information from this study may benefit other patients with cervical DDD or spondylosis in the future. The risks linked to the device or the surgery are the same whether the patient participates in the study or not. The risks of participating in the study are the risks linked to the exposure to the x-rays and CT scans as some of them are extra to the standard of care of the patient.

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 December 2025

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

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
301656

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
P83_CLD001, IRAS 301656

Study information

Scientific Title
Prospective evaluation of clinical and radiographic outcomes after anterior cervical interbody fusion surgery using a TRYPTIK® Ti-Life cage

Acronym

Tryptik Ti

Study objectives
The sample size of 60 study participants allows for detection of the primary endpoint of 95% in the target population with 80% power at two-sided 5% significance.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. France: Approved 25/01/2022, Comite De Protection Des Personnes Nord Ouest Iii (CPP Nord Ouest III - CHU Caen, 14033 Caen cedex 9, France; +33 (0)9 64 08 19 44; cppnordouest3@orange.fr), ref: SI RIPH 2G : 21.04209.000054
2. Spain: Approved 18/01/2022, Comite De Ética De La Investigacion De La Fundacion Jimenez Diaz (CEImFJD) (Fundación Instituto Investigación Sanitaria FJD, Comité de Etica de la Investigación FJD, C/Isaac Peral nº 42 (Oficinas), 2ª planta, 28015 Madrid, Spain; +34 (0)91 550 48 00 – ext 4492; ceic@fjd.es), ref: EO177-21_HGV
3. UK: Approved 14/03/2022, HRA and Health and Care Research Wales (HCRW) (Ground Floor, Skipton House, 80 London Road, London, SE1 6LH, UK; Tel: not provided; approvals@hra.nhs.uk, HCRW.approvals@wales.nhs.uk), ref: 21/WA/0155

Study design
Prospective interventional single-arm multicentric study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Radiculopathy and/or myelopathy, secondary to cervical degenerative disc disease and/or spondylosis, and for patients who are resistant to conservative management

Interventions
TRYPTIK Ti is intended for use during Anterior Cervical Discectomy and Fusion (ACDF), between C3 and C7, and up to four consecutive levels. It is indicated for the surgical treatment of radiculopathy and/or myelopathy, secondary to cervical DDD and/or spondylosis, and for patients that are resistant to conservative management.

The TRYPTIK® Ti cervical Interbody Devices are to be used with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion.

The TRYPTIK® Ti implants must be used with a supplemental internal spinal fixation system that has been cleared for use in the cervical spine.

Enrollment period is estimated to be 12 months with up to 24 months postoperative follow-up.

Intervention Type
Device

Phase
Phase IV

Drug/device/biological/vaccine name(s)
TRYPTIK® Ti cervical Interbody Device

Primary outcome(s)
Fusion rates assessed by the use of reconstructed axial and coronal fine-cut computed tomography scans (CT scan) at 6-month postoperative visits. Assessment will be repeated at 12 and 24 months only if solid fusion is not reached on the previous assessment. Fusion will be assessed as solid fusion, fibrous union, or non-union by an independent orthopedic or neurosurgeon and a radiologist consultant who will interpret the CT scans. A third independent orthopedic or neurosurgeon consultant will adjudicate differences in fusion findings.

Key secondary outcome(s))
1. Intervertebral foraminal height measured on radiographs, defined as the distance between the lower margin of the upper pedicle to the upper margin of the lower pedicle, assessed immediately postoperatively and at 6-12 weeks, 6, 12 and 24 months post-operatively compared to the preoperative measures
2. Cervical and segmental lordosis assessed immediately postoperatively and at 6-12 weeks, 6, 12 and 24 months post-operatively compared to the preoperative measures. Lateral radiographs of the cervical spine will be used to measure cervical and segmental lordosis by means of the Cobb angle. Segmental sagittal alignment is defined as the angle between the cranial and caudal endplates of the vertebrae located above and below the affected segment, and cervical sagittal alignment from C1 to C7. Both measures provide positive and negative values indicating lordotic or kyphotic angulation, respectively.
3. Subsidence rate balance assessed at 6-12 weeks, 6, 12 and 24 months post-operatively compared to the immediate postoperative measure.
Implant subsidence will be evaluated by means of lateral radiographs of the cranial and caudal endplates of the segments located above and below the operated segments, respectively. Measurement of the distance between the superior endplate of the superior vertebral body and the inferior endplate of the inferior vertebral body are based on the anterior (AntEH) and posterior endplate height (PostEH). Based on location, implant subsidence will be classified according to four directions of implant sinkage: anterior, posterior, cranial, and caudal. Subsidence will be considered mild if the loss of height is under 3 mm, and severe if the loss is over 3 mm
4. Patient-reported outcomes:
4.1. Functional capacity assessed by the Neck Disability Index (NDI) at baseline (preoperative status) to 6-12 weeks, 6-, 12- and 24-months postoperative
4.2. Health-related quality of life assessed by the SF-12 at baseline (preoperative status) to 6-12 weeks, 6-, 12- and 24-months postoperative
4.3. Pain and change in pain (arm and neck) assessed using VAS arm and neck pain scores at baseline (preoperative status) to 6-12 weeks, 6-, 12- and 24-month postoperative
4.4. Patient satisfaction evaluated using a satisfaction questionnaire at 12 and 24 months
5. Safety: incidence of adverse events (AEs) related to the device and/or procedure recorded from the surgery through the 24 months postoperative follow-up. All perioperative and postoperative ADEs and SAEs will be assessed for the relationship to device and procedure, seriousness, incidence, and time to resolution or re-operation. Incidence of re-intervention at the index level will be assessed.

Completion date

01/12/2025

Eligibility

Key inclusion criteria
1. Patients who will receive at least one and up to four TRYPTIK® Ti-Life cages between C3 and C7 levels
2. Patient willing and able to comply with follow-up schedule and filling out questionnaires
3. Written voluntary informed consent signed

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
96

Key exclusion criteria
1. Patients under 18 years of age
2. Patients in whom cervical/radicular pain could be attributable to a diagnosis other than degenerative disease (i.e., tumors, congenital, rheumatoid disease, or infection)
3. Patients who have a contraindication listed in the IFU

Date of first enrolment
01/11/2021

Date of final enrolment
19/12/2023

Locations

Countries of recruitment
United Kingdom

England

Spain

Study participating centre

Hospital Universitario General de Villalba
Carretera de Alpedrete a Moralzarzal M-608 Km 41
Collado Villalba Madrid
Spain
28400

Study participating centre
NHS North Tyneside CCG
12 Headly Court
Orion Business Park
North Shields
United Kingdom
NE29 7ST

Study participating centre
Hospital Clínico Universitario De Valencia
Av. de Blasco Ibañez, 17
Valencia
Spain
46010

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 raw patient data is not expected to be made available and will be held at the sponsor level.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes