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Evaluation of the safety and the performance of the TRYPTIK2®C-Plate Cervical Plate System on patient treated for cervical degenerative disease or trauma

Submission date
25/01/2023

Recruitment status
No longer recruiting

Registration date
31/01/2023

Overall study status
Completed

Last Edited
26/01/2023

Condition category
Nervous System 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 look at how well a device called the TRYPTIK2®C-Plate works in a type of surgery called Anterior Cervical Discectomy and Fusion (ACDF) for people with Degenerative Disc Disease (DDD), spondylosis, or trauma. The TRYPTIK2®C-Plate is made up of different sizes of plates and screws that are used to hold the spine in place. The screws have a special locking feature that keeps them from coming loose. The study will see how well this device works, if it has any benefits and if it is safe to use.

Who can participate?
The device is used for its intended use and patients represent the intended population. All patients required an anterior cervical discectomy with fusion, between C2 and C7 and up to 4 consecutive levels, due to symptomatic cervical degenerative disc disease (CDDD), after unsuccessful non-operative treatment.

What does the study involve?
Retrospective data will be collected for patients who underwent surgery between 2018 and 2020. All visits are standard and data collected will consist in pre-operative, surgery, post-operative before discharge, post-surgery at approximately 1-6 months, at ≥12 months and at the last follow up at enrollment (prospective visit). The study does not involve additional examinations.

What are the possible benefit 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 TRYPTIK®2C-Plate as a part of the Post-Market Surveillance.
There is no risk inherent to the study participation as this is a retrospective study that does not involve any additional examinations for the patients.

Where is the study run from?
Spineart (Switzerland)

When is the study starting and how long is it expected to run for?
April 2021 to April 2022

Who is funding the study?
Spineart (Switzerland)

Who is the main contact?
clinic@spineart.com

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
P65_CLD001

Study information

Scientific Title
Evaluation of clinical and radiographic outcomes after cervical arthrodesis surgery using a TRYPTIK2®C-Plate Anterior Cervical Plate System

Acronym
Tryptik 2C-Plate

Study objectives
Evaluation of the performance and safety of the Tryptik 2C-Plate device in the treatment of myelopathy and/or radiculopathy, or trauma.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 02/06/2021, Comité de Ética de la Investigación con medicmentos (CElm del Hospital Clínoco Universitario de Valencia; +34 96 1973976; ceic_hvc@gva.es) ref. 94/21

Study design
Observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet.

Health condition(s) or problem(s) studied
Myelopathy and/or radiculopathy, or trauma

Interventions
Retrospective study which will include approximately 70 CDDD consecutive patients (depending on the recruitment) having received the TRYPTIK®2C-Plate Anterior Cervical Plate between 2018 and 2020, to evaluate the performance and safety of the device.
The pre-operative data, surgical data, discharge data and short to medium term follow-up data (Visit 4: 1-6 months after surgery, Visit 5: ≥12 months after surgery) were collected retrospectively. No randomization or blinding took place during the study. One prospective visit was performed after the patient was enrolled to collect the patient self-assessment questionnaires and to answer safety questions. The data collection will reflect the site standard practice and the IFU.

Intervention Type
Device

Phase
Phase IV

Drug/device/biological/vaccine name(s)

TRYPTIK®2C-Plate Anterior Cervical Plate

Primary outcome measure
1. Performance assessed qualitatively by radiological imaging at ≥12 months:
1.1. Stability: Preservation of the implant position: good, absent
1.2. Absence of mobility chambers around the screws: yes, no
2. Safety assessed by the rate of device failure, defined as revision surgery; cage or screw migration; screw pullout; clip disconnection; cage, plate, screw fracture; plate failure; device component misplacement measured using patient records.

Secondary outcome measures
1. Evaluation of safety associated with the implantation of Tryptik 2C Plate, from surgery and up to the last follow-up (Safety assessment intra-operatively and post-surgery by reporting the incidence and time to resolution of all complications and adverse events related to the medical device and/or procedure, including all surgical revisions).
2. Evaluation of the performance of Tryptik 2C Plate assessed at approximately 1-6 months post-surgery as per standard practice.
3. Clinical and neurologic evaluation pre-operatively and post-surgery at approximately 1-6 months and at ≥12 months per standard practice.
4. Pain evaluation by self-reported VAS questionnaire at last follow-up post-surgery.
5. Assessment of Neck Disability Index, by the self-reported NDI questionnaire at last follow-up post-surgery.
6. Quality of life in relation to health and patient satisfaction through the self-reported SF-12 questionnaire at last follow-up post-surgery.
7. Assessment of time to return to work post-surgery.
8. Fusion of the interbody cage at the treated levels: acquired, in progress, absent, pseudoarthrosis at approximately 1-6 months and at ≥12 months post-surgery as per standard practice.
9. Evaluation of the TRYPTIK®2C-Plate instrumentation supporting the surgery.

Overall study start date
01/04/2021

Completion date
22/04/2022

Eligibility

Key inclusion criteria
1. Aged over 18 years
2. Patients who have received one TRYPTIK®2C-Plate as per the IFU
3. Informed consent/Information letter signed

Participant type(s)
Patient

Age group
Adult

Lower age limit

18 Years

Sex
Both

Target number of participants
70

Total final enrolment
42

Key exclusion criteria
Off label surgeries

Date of first enrolment
27/09/2021

Date of final enrolment
22/04/2022

Locations

Countries of recruitment
Spain

Study participating centre
Hospital Clínico Universitario de Valencia
Av. de Blasco Ibáñez, 17
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Sponsor information

Organisation
Spinart SA

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Sponsor type
Industry

Website
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Funder(s)

Funder type
Industry

Funder Name
Spineart SA

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
30/09/2023

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

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