

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	<input type="checkbox"/> Prospectively registered
Registration date 31/01/2023	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 26/01/2023	Condition category Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
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 medicamentos (CEIm del Hospital Clínico Universitario de Valencia; +34 96 1973976; ceic_hvc@gva.es) ref. 94/21

Study design

Observational cohort study

Primary study design

Observational

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

Valencia

Spain

46010

Sponsor information

Organisation

Spinart SA

Funder(s)

Funder type

Industry

Funder Name

Spineart SA

Results and Publications

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