

Neck stabilization using the PERLA® Occipital fixation system

Submission date 23/11/2022	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 15/12/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 11/04/2025	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

This is a post-market study to confirm the performance and safety of the PERLA Occipital-Cervical-Thoracic system in the treatment of head-neck instability due that can be due to trauma, autoimmune disease, oncologic (cancer) or congenital (present from birth) reasons. This treatment results in severe restriction of head movement after surgery. Therefore, this method should be restricted to patients with head-neck instability as a last resort. The medical devices to stabilise the head-neck junction are composed of occipital plates, rods, and a screw system such as the PERLA Occipital-Cervical-Thoracic system. Head-neck fixation is the treatment of choice in most cases of traumatic occipito-cervical dislocation. It is recommended in the most recent guidelines from the American Association of Neurological Surgeons (AANS)/Congress of Neurological Surgeons (CNS) Joint Guidelines Committee.

Who can participate?

Patients who received the PERLA Occipital plate at the participating centers

What does the study involve?

The site will review the medical charts of patients who received the investigated device. Those patients who are eligible for the study will be contacted to invite them to participate in the study. After reading the information letter, the patients should let their surgeon know if they agree/consent before any data collection. Clinical and x-ray data will be collected for preoperative, surgical, and postoperative clinical visits performed as the site standard of care.

What are the possible benefit and risks of participating?

As a retrospective study of real-world evidence data collection, there are no direct benefits or risks.

Where is the study run from?

Three hospitals or clinic in France, Germany and Austria

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

June 2022 to July 2024

Who is funding the study?
Spineart (Switzerland)

Who is the main contact?
clinic@spineart.com

Study website

<https://www.health-data-hub.fr/projets/stabilisation-de-la-colonne-occipito-cervicale-avec-lutilisation-de-la-fixation-occipito>

Contact information

Type(s)

Scientific

Contact name

Mrs Dervilla Bermingham

Contact details

Chemin du Pré-Fleuri 3
Plan-les-Ouates
Switzerland
1228
+33 (0)225701200
dbermingham@spineart.com

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

P69_CLD002

Study information

Scientific Title

Occipitocervical spine stabilization using PERLA® posterior occipito-cervico-thoracic fixation. A post-market clinical follow-up study

Acronym

PERLA Occipital plate

Study objectives

N/A. Non-probability sample size, due to the very low number of patients treated. The study is to confirm the performance and safety of the Perla Occipital plate for the treatment of instabilities in the craniocervical junction by collecting real-world evidence.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. France: Since it's a fully retrospective study, only a registration on the Health Data Hub platform is needed; no contact details, website: <https://www.health-data-hub.fr/projets>; submission date 26/10/2022, ref: F20221026145427
2. Germany: Approved 20/03/2023, Ethik-Kommission der Bayerischen Landesärztekammer (EK der BLÄK, Mühlbauerstraße 16, 81677 München, Germany; +49 (0)89 4147 283; ethikkommission@blaek.de), ref: 22126
3. Austria: Approved 15/03/2024, Medizinische Universität Graz (Neue Stiftingtalstr.6, West, Q /04, 8010 Graz, Austria; +43 (0)316 385 13928; ethikkommission@medunigraz.at), ref: 36-121 ex 23/24

Study design

Real-world evidence retrospective multicentric international single-arm post-market clinical follow-up study

Primary study design

Observational

Secondary study design

Retrospective study

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format. Please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied

Acute or chronic cranio-cervical junction instability due to, but not limited to: Trauma: Atlanto-occipital dislocation, occipital condyle fracture, atlas, and axis fractures; Inflammation /autoimmune disease: Rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, inflammatory bowel disease-associated arthropathy, tuberculosis, osteomyelitis; Neoplasm: Metastasis, chordoma, Ewing tumor, osteoblastoma, osteochondroma, hemangioma, aneurysmal bone cyst; Congenital: Chiari malformation with basilar invagination, Down's syndrome, Klippel-Feil syndrome, Morquio's syndrome, os odontoideum; Iatrogenic: After odontoidectomy, failed previous attempts at C1-C2 fusion, after the far lateral approach with occipital condyle resection.

Interventions

Any patient who has received a Perla Occipital system in the participating center will be asked for the data collection of their retrospective data.

Intervention Type

Device

Phase

Phase IV

Drug/device/biological/vaccine name(s)

Perla® Occipital System

Primary outcome measure

1. Spinal stability assessed by measuring the COBB angle on radiological images. The stability will be achieved by a maximum change of 5° of the COBB angle of the first postoperative follow-up (up to 4 months) interim (4-10 months) and last follow-up (after 10 months) radiological exams compared to the immediate postoperative radiological exams
2. Fusion (solid, fibrous, non-union) assessed with radiological images at interim postoperative follow-up (4-10 months) and last follow-up (after 10 months)
3. Clinical and neurological assessment will be evaluated with the Modified Japanese Orthopaedic Association (mJOA) scale. The mJOA scores at immediate postoperation, first follow-up (up to 4 months) interim (4-10 months) and last follow up (after 10 months) will be compared to the pre-operative score. Additionally, score groups analysis over time will be assessed (scores 0-11; 12-14; 15-18).
4. Absence of adjacent segment disease will be assessed with clinical and radiological assessments at interim postoperative follow-up (4-10 months) and last follow-up (after 10 months)
5. Safety evaluation: The incidence of AEs related to the device and/or procedure will be recorded from the surgery through the last post-operative follow-up visit. All perioperative and postoperative adverse device effects (ADEs) (including serious adverse device effects [SADEs] and unanticipated serious adverse device effects [USADEs]) will be assessed for the relationship to device and procedure, seriousness, incidence, and time to resolution or re-operation. The incidence of re-intervention at the index level will be assessed. The incidence of device deficiencies that might have led to a SADE will be recorded from the surgery through the last post-operative follow-up visit.

Secondary outcome measures

There are no secondary outcome measures

Overall study start date

01/06/2022

Completion date

03/07/2024

Eligibility

Key inclusion criteria

1. Patients who received the PERLA® Occipital system to treat a cranio-cervical instability of any cause and indicated for occipito-cervical fusion
2. Non-opposition/consent for retrospective data collection

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

20

Total final enrolment

15

Key exclusion criteria

Current exclusion criteria as of 19/02/2024:

Does not meet the inclusion criteria.

Previous exclusion criteria:

Less than 6 months of post-operative follow-up

Date of first enrolment

09/03/2023

Date of final enrolment

26/05/2024

Locations

Countries of recruitment

Austria

France

Germany

Study participating centre

HIA Sainte Anne - Toulon

2 Bd Sainte-Anne

Toulon

France

83000

Study participating centre

Klinik für Orthopädie, Unfallchirurgie und Wirbelsäulentherapie Donau-Ries Klinik Donauwörth
Neudegger Allee 6
Donauwörth
Germany
86609

Study participating centre

Landeskrankenhaus Hochsteiermark, Standort Bruck
Tragösser Str. 1
Bruck an der Mur
Austria
8600

Sponsor information

Organisation

Spineart (Switzerland)

Sponsor details

Chemin du Pré-Fleuri 3
Plan-les-Ouates
Switzerland
1228
+33 (0)225701200
clinic@spineart.com

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

Planned publication in a peer-reviewed journal.

Intention to publish date

31/12/2025

Individual participant data (IPD) sharing plan

The dataset generated and analysed during the current study will be available upon request from clinic@spineart.com

IPD sharing plan summary

Available on request