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Neck stabilization using the PERLA® Occipital fixation system

Submission date	Recruitment status	[X] Prospectively registered
23/11/2022	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
15/12/2022	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
11/04/2025	Musculoskeletal Diseases	[X] 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

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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, Mühlbaurstraße 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

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s))
There are no secondary outcome measures

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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)

ROR
https://ror.org/05sz2c652

Funder(s)

Funder type
Industry

Funder Name
Spineart SA

Results and Publications

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes