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Clinical evaluation after surgery using the PERLA® TL system for the treatment of spinal deformities.

Submission date
15/01/2025

Recruitment status
Recruiting

Registration date
16/01/2025

Overall study status
Ongoing

Last Edited
06/08/2025

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Spinal deformities are abnormal curvatures or shapes of the spine that can affect individuals of all ages. These deformities can be congenital, developmental, or acquired due to various conditions such as neuromuscular disorders, degenerative changes, or trauma. They can cause pain, functional impairment, and in severe cases, significant health complications. The most common types of spinal deformities include scoliosis, hyperkyphosis and lordosis. Spinal deformities are a diverse group of conditions that can significantly impact an individual's life. Adolescent Idiopathic Scoliosis (AIS) and Adult Spinal Deformity (ASD) are two most common. Treatment approaches may vary internationally. Depending on the type/severity of the curvature and the patient's stage of growth (if applicable), the treatment includes conservative treatment (observation, bracing, physical therapy/exercise, etc) and surgical options. It is important to note that the treatment approach should be individualized based on the patient's specific condition, curve severity, and skeletal maturity (if applicable). The decision-making process should involve a multidisciplinary team, including spine surgeons, pediatricians (if applicable), and physical therapists. Posterior screw fixation is an established surgical technique for the treatment of spinal instabilities and deformities. Perla® TL / Perla® TL MIS spine system is a thoracic, lumbar, and sacral posterior osteosynthesis system on the market since 2020. It was designed to adapt to the patient’s anatomic variations. This Post-Market Clinical Follow-Up (PMCF) study will assess the system when used to treat spinal deformity in two separate groups of patients: the ASD group and the AIS group. Each group will be analyzed independently. The patients are divided into these 2 groups because they represent the majority of the patients with spinal deformities requiring spine surgery. This study aims to confirm the safety, performance and clinical benefit of the Perla® TL/ Perla® TL MIS system in these two populations.

Who can participate?
Patients scheduled for surgery with the Perla® TL system to treat spinal deformities (ASD or AIS), who are willing and able to comply with follow-up visits and fill out questionnaires.

What does the study involve?
The pre-operative visit data, the surgical data, discharge data and post-operative data at 2-6 months, 12 months (±2 months), and 24 months (±2 months) will be collected prospectively. All these visits are done as per the standard of care (SoC) in the selected sites. Only the patients' questionnaires collected at the preoperative visit and at the follow-up visit PO (SRS-22r, SAQ, ODI, BP-VAS, LP-VAS, EQ-5D) are not always performed in SoC by the sites. There is no risk for the patient to complete the additional questionnaire for the study.

What are the possible benefits and risks of participating?
There are no direct medical benefits for the patients participating, but the data collected may help other patients.

There is no risk in participating in this study. The risks associated with Perla® TL are the same whether or not the patients take part in the study (surgery already planned as per SoC).

Where is the study run from?
Spineart SA (Switzerland)

When is the study starting and how long is it expected to run for?
May 2024 to December 2028. February 2025 (first SIV) to June 2028 (Close out visit).

Who is funding the study?
Spineart SA (Switzerland)

Who is the main contact?
clinic@spineart.com

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
P79_CLD001

Study information

Scientific Title
Evaluation of clinical and radiographic outcomes following spinal surgery using the Perla® TL posterior osteosynthesis system for the treatment of spinal deformities over a period of up to 24 months.

Acronym
PERLA® TL Deformity

Study objectives
The study's aim is to collect clinical evidence to confirm, under MDR 2017/745, the safety, performance and clinical benefit of the Perla® TL system (approved on the market under the MDD since 2020). The purpose is to confirm that the Perla® TL system is as performant and safe compared to performance data for similar other currently marketed systems and profits from an acceptable benefit/risk profile for its intended use. The study is evaluating two separate groups of patients: Adult Spinal Deformities (ASD) and Adolescent Idiopathic Scoliosis (AIS). Each group will be analyzed independently by evaluating the Patient Reported Outcomes (PRO) and assessing radiological image's quantitative parameters pre-and post-surgery.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 31/12/2024, Comité de protection des personnes Ouest III (CHU La Milétrie, POITIERS, 86021, France; +33 (0)5 16 60 42 27; cpp-ouest3@chu-poitiers.fr), ref: 2024-A02379-38

2. Approved 17/02/2025, CEIm Fundació Sant Joan de Déu (Fundació Sant Joan de Déu, C/ Santa Rosa 6, Esplugues de Llobregat - Barcelona, 08950, Spain; +34 93 600 97 32 (Ext.: 77808); frecerca.ceic@sjd.es), ref: CI. PS-13-24

Study design
Prospective non-randomized international multicentric post-marketing clinical follow-up study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital, Medical and other records

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
The Perla® TL / Perla® TL MIS, including various types of implant, is suitable for the stabilisation of spinal segments in the surgical treatment of chronic instabilities or deformities of the thoracic, lumbar, and sacral spine of Adolescent Idiopathic Scoliosis (AIS) and Adult Spinal Deformities (ASD)

Interventions
This is a prospective, international, multicentric post-market clinical follow-up study (PMCF) on patients receiving Perla® TL to treat spinal deformities. The study is divided into 2 independent non-randomized groups which are the ASD (group 1), and the AIS (group 2).

It has been demonstrated that posterior screw fixation is an established surgical technique for the treatment of TL spine instabilities due to spinal deformities, mainly scoliosis, hyperkyphosis and lordosis. The methodology of this PMCF study includes data collection of patient questionnaires ODI or SRS-22r scores (depending on the group), EQ-5D and VAS (leg and back), discharge and return to work/school, radiological images and safety events reporting.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Perla® TL/ PERLA®TL MIS system

Primary outcome measure
The clinical benefit of the Perla® TL system will be demonstrated on the Performance Analysis Set by evaluating the Patient Reported Outcomes (PROs) at 12 months post-operatively using the Oswestry Disability Index (ODI) self-reported questionnaire for the ASD (Group 1) and the SRS-22 (Scoliosis Research Society) for the AIS (Group 2).

For Group 1 (ASD): The benefit will be confirmed by comparing the ODI scores between preoperative (V1) with scores of 2-6 months visit (V4) and 12 months visit (V5) post-operative.

For Group 2 (AIS): The benefit will be evaluated by comparing the SRS-22 questionnaire scores between pre-operative (V1) with scores of 2-6 months visit (V4) and 12 months visit (V5) post-operative.

Secondary outcome measures
1. To confirm the performance of the Perla® TL system within 24 months post-operatively by quantitatively comparing and assessing the radiological images (Coronal Cobb Angle, Coronal

Alignment, Thoracic Kyphosis angle, Lumbar Lordosis angle, Pelvic Incidence, Sacral Slope, Pelvic Tilt, Sagittal Vertical Axis and Odontoid to Hip Axis angle) of the pre-operative visit (V1), discharge (V3), 2-6 months visit (V4), 12 months visit (V5) and 24 months visit (V6).

2. To confirm the clinical benefit of the Perla® TL system within 24 months post-operatively by quantitatively comparing the scores of the PRO questionnaires VAS (back and leg), EQ-5D, Spinal Appearance Questionnaire "SAQ" (only AIS group) and the SRS-22r (only AIS group) or ODI (only ASD group) from baseline (V1) and all post-operative visits (V6).

3. The safety will be assessed by analysing the number of different types of Adverse Event incidences during the study.

Overall study start date
01/05/2024

Completion date
31/12/2028

Eligibility

Key inclusion criteria
Patients must meet all the below inclusion criteria (for screening):
1. Patients scheduled for surgery with the Perla® TL system to treat spinal deformities (ASD or AIS)
2. Patients who are willing and able to comply with follow-up visits and fill out questionnaires
3. Written voluntary informed consent signed by the patients and if applicable, their legal representative (for minors)

Per-operative inclusion criteria (for enrolment):
Patients with the surgery completed with the Perla® TL system

Participant type(s)
Patient

Age group
Mixed

Lower age limit
10 Years

Upper age limit
99 Years

Sex
Both

Target number of participants
50 subjects in the adult deformities (group 1)/50 subjects in the Adolescent Idiopathic Patient (group 2)

Key exclusion criteria
1. Adult deprived of their freedom by administrative or legal decision or under guardianship
2. Patients with a contraindication as per IFU

Date of first enrolment
19/03/2025

Date of final enrolment
28/02/2026

Locations

Countries of recruitment
France

Spain

Study participating centre
Hôpital Privé Francheville
4 Pl. Francheville
Périgueux
France
24000

Study participating centre
Clinique Charcot
51 Rue Commandant Charcot
Sainte-Foy-lès-Lyon
France
69110

Study participating centre
Hospital San Joan de Deu
Passeig de Sant Joan de Déu, 2
Esplugues de Llobregat, Barcelona
Spain
08950

Study participating centre
Hospital de La Arrixaca Murcia
Ctra. Madrid-Cartagena, s/n

El Palmar, Murcia
Spain
30120

Study participating centre
Hospital del Niño Jesús
C/ Menéndez Pelayo, 65, Retiro
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Study participating centre
Hospital Nuestra Señora del Rosario
C/ Principe de Vergara 53
Madrid
Spain
28006

Study participating centre
Hospital del Mar
Marítim de la Barceloneta, 25, 29
Ciutat Vella
Barcelona
Spain
08003

Sponsor information

Organisation
Spineart (Switzerland)

Sponsor details
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Sponsor type
Industry

Website
https://www.spineart.com/

ROR
https://ror.org/05sz2c652

Funder(s)

Funder type
Industry

Funder Name
Spineart (Switzerland)

Results and Publications

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

Intention to publish date
01/12/2029

Individual participant data (IPD) sharing plan
The dataset generated and analysed during the current study will be available upon request from clinic@spineart.com. The type of data that will be shared: clinical data of the study. Dates of availability: up to 2040. Participants will be required to provide consent. All subjects' data are pseudo-anonymized. There are no ethical or legal restrictions.

IPD sharing plan summary
Available on request