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sPinal coRd stimulatiOn coMpared with lumbar InStrumEntation for low back pain after previous lumbar decompression (PROMISE): a prospective multicentre RCT

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ABSTRACT

Introduction Persistent spine pain syndrome type 2 (PSPS2) represents a significant burden to the individual and society. Treatment options include revision surgery, stabilisation surgery of the spine, neuromodulation, analgesics and cognitive behavioural therapy. Nevertheless, structured treatment algorithms are missing as high-level evidence on the various treatments is sparse. The aim of this study is to compare higher frequency neuromodulation with instrumentation surgery in patients suffering from PSPS2.

Methods and analysis The sPinal coRd stimulatiOn coMpared with lumbar InStrumEntation for low back pain after previous lumbar decompression (PROMISE) trial is a prospective randomised rater blinded multicentre study. Patients suffering from PSPS2 with a functional burden of Oswestry Disability Index (ODI) >20 points are randomised to treatment via spinal cord stimulation or spinal instrumentation. Primary outcome is back-related functional outcome according to the ODI 12 months after treatment. Secondary outcomes include pain perception (visual analogue scale), Short Form-36, EuroQOL5D, the amount of analgesics, the length of periprocedural hospitalisation and adverse events. Follow-up visits are planned at 3 and 12 months after treatment. Patients with previous lumbar instrumentation, symptomatic spinal stenosis, radiographical apparent spinal instability or severe psychiatric or systemic comorbidities are excluded from the study. In order to detect a significant difference of ≥10 points (ODI) with a power of 80%, n=72 patients need to be included. The recruitment period will be 24 months with a subsequent 12 months follow-up. The beginning of enrolment is planned for October 2022.

Ethics and dissemination The PROMISE trial is the first randomised rater blinded multicentre study comparing the functional effectiveness of spinal instrumentation versus neuromodulation in patients with PSPS2 in order to achieve high-level evidence for these commonly used treatment options in this severely disabling condition. Patient recruitment will be performed at regular outpatient clinic visits. No further (print, social media) publicity is planned. The study is approved by the local ethics committee (LMU Munich, Germany) and will be conducted according to the Declaration of Helsinki.

Trial registration number NCT05466110.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ First multicentre randomised controlled trial to compare spinal cord stimulation versus instrumentation in persistent spine pain syndrome type 2.
⇒ Blinded analysis.
⇒ 'Real-life' inclusion criteria.
⇒ Meaningful study hypothesis in a hard-to-treat but common disease.
⇒ Various surgical techniques in 'fusion group'.

INTRODUCTION

Low back pain affects people of all ages and has become the leading cause of living with disability worldwide.[1] In patients with degenerative disc disease and failed conservative treatment, surgery is warranted. However, not all patients will have a sustained relief of symptoms following surgery. In the absence of an anatomical correlate, these patients are defined as having a 'failed back surgery syndrome' or persistent spine pain syndrome type 2 (PSPS2).[2–4] For patients with PSPS2 and predominant back pain, the optimal treatment modality remains controversial.

The only prospective randomised study for patients with chronic low back pain following previous decompressive lumbar surgery compared spinal fusion with cognitive intervention and exercises and showed no significantly different success rates (defined as ≥10 points improvement in the Oswestry Disability Index (ODI)) of either treatment.[5]

Success rates were overall mediocre with 50% and 48%, respectively.[5]

Recently, new techniques in neuromodulation are applied successfully for the treatment of PSPS2 with predominant back pain.[6–9] Especially higher frequency spinal cord stimulation (SCS) was reported to be effective for both leg and back pain compared with conventional SCS paradigms.[7 10] More than 60% of patients experienced an ODI improvement of ≥10 points after 1 year.

SCS and spinal instrumentation are currently in clinical practice for the treatment of PSPS2. Instrumentation constitutes the standard of care with known long-term results.[5] However, the perisurgical morbidity is higher as in SCS procedures.[6 11–14] For SCS, preliminary data suggest favourable results for the treatment of PSPS2 but there is a risk of long-term failure.[6] The sPinal coRd stimulatiOn coMpared with lumbar InStrumEntation for low back pain after previous lumbar decompression (PROMISE) trial aims to prospectively compare spinal instrumentation and SCS as treatment for PSPS2. The purpose of this study is to describe the design of PROMISE and discuss some of its strengths and limitations.

MATERIALS AND METHODS

Trial goals and objective

The objective of PROMISE is to prospectively compare the treatment effect of SCS and spinal instrumentation in PSPS2 according to back-related disability 12 months after intervention. Peri-interventional safety, adverse events (AEs) and radiological features will be evaluated.

Study sites

Five study centres will recruit patients for PROMISE (box 1).

Ethics and dissemination

The study will be conducted in accordance with the recommendations of guiding physicians in medical research involving human subjects by the World Medical Association Declaration of Helsinki. Ethics approval is granted by the local ethics committee (EC) of the trial coordinators site (LMU Muenchen; Nr: 22-0221) and will be reviewed by the local EC of each participating centre. An informed consent will be obtained for each participant by the local investigators. The trial protocol is registered at clinicaltrials.gov (NCT05466110). Potential subjects are identified as eligible by the local investigators among their patients during hospitalisation or in the outpatient clinic. Eligible patients are informed about the study by the local investigators through personal discussion of the study aims, time course, procedures, interventional arms including contemporary information about risks and functioning of either treatment supported by a written patient information in lay language. Informed consent is obtained from patients who are willing and eligible to participate. Data regarding demographic characteristics, medical history and comorbidities, symptoms (bothersomeness and frequency) and baseline measurements for all outcomes are obtained via a combination of patient interview, patient self-administered survey and physician survey. All data are collected via paper case report forms (CRF).

Box 1 List of participating centres

University Hospital Augsburg, Germany, Department of Neurosurgery (trial coordination)
University Hospital Bonn, Germany, Department of Neurosurgery
University Hospital Heidelberg, Germany, Department of Neurosurgery
Hospital Memmingen, Germany, Department of Neurosurgery
Municipal Hospital of Munich/Bogenhausen, Germany, Department of Neurosurgery

Inclusion criteria

Patients with previous decompressive or disc surgery of the lumbar spine are included. Minimum age for inclusion is 18 years. There is no upper age limit. Patients must have undergone non-surgical treatment of PSPS2 for a minimum of 6 months (possibly including epidural steroid injections, facet joint denervation, physical therapy, oral analgesics including opioids and antineuropathics).

Exclusion criteria

- Previous surgery for lumbar instability (fusion or non-fusion techniques, ie, interspinous devices);
- Olisthesis greater than grade I according to the Meyerding classification;
- Isthmic spondylolysis (with or without olisthesis);
- Apparent spinal instability defined as a slippage of at least 5 mm or segmental vertebral motion of at least 3 mm or 12° on flexion/extension X-ray;
- Symptomatic lumbar spinal stenosis;
- Patients with less severe symptomatology (ODI ≤20 points);
- Major comorbidities including systemic illnesses like rheumatoid arthritis, osteoporosis, known malignancy, severe cardiopulmonary disease as well mental illnesses (major depression, dementia, schizophrenia);
- Pregnancy.

Assignment to intervention/randomisation

Assignment to intervention is performed in a randomised way. Allocation of treatments will be performed centrally at the principal investigators site using a computer-generated list. Subsequent treatment group allocation of patients will be communicated and documented by the use of randomisation letters.

Study interventions

Both treatment modalities, SCS as well as spinal instrumentation surgery are current practice and approved for the treatment of PSPS2.

Spinal cord stimulation

SCS is a neuromodulation technique by which electric current is applied directly on the spinal cord via epidural

electrodes and an implanted pulse generator (IPG). Percutaneous leads are implanted in the epidural space of the thoracic spine during the initial procedure. After discharge, a trial phase of 5–10 days is initiated and performed according to local preferences and standard of operations. Patients are monitored for any complications and pain reduction. If a significant pain reduction (>50% on the visual analogue scale (VAS) for back or leg pain) is achieved, the permanent IPG is implanted. If the therapy remains non-beneficial throughout the trial phase, the leads will be explanted. In this trial, the SCS device WaveWriter Alpha (Boston Scientific Corporation, Marlborough, Massachusetts, USA) is used. It is an established and worldwide licensed device.

Spinal fusion surgery

Spinal instrumentation will be performed according to local preferences and standard operating procedures including single or multilevel screw-rod stabilisation systems with or without ventral fusion surgery (eg, anterior/lateral/transforaminal or posterior lumbar interbody fusion) or posterolateral fusion. The specific details of surgery in any case will be documented. This control group aims to represent the gold standard of care of current practice.[15] Safety and efficacy of these fusion techniques have been repeatedly proven.[5 11 16]

Additional treatment

Postoperative care is not standardised in the study protocol and is to be performed according to the standard of care for lumbar fusion surgery or SCS at the treating centre. The use of analgesics follows the local routine, but needs to be documented in detail. Further non-surgical treatments (such as physical therapy, education/counselling with home exercise, steroid injections, facet joint infiltrations) include therapies prescribed by the treating physician or therapies the patients initialised on their own. Participating physicians agree to avoid the use of any experimental devices or biologics during treatment. However, if the physician decides during surgery that the patient requires a procedure that differs from these protocols, he or she is instructed to perform that preferred procedure and record the details.

Crossover

Patients are allowed to crossover in the fusion group at any point of time. This includes conditions after a non-beneficial SCS trial with subsequent explantation.

Study timetable

The enrolment period is 24 months, with each patient undergoing follow-up visits at 3 and 12 months after intervention (either spinal instrumentation or SCS). Spinal imaging consisting of MRI and CT scans as well as dynamic flexion-extension radiographs are performed before intervention and after 12 months (table 1). The study will start recruiting patients from October 2022 onwards.

Table 1 Study timeline

	Baseline	Intervention (start of RCT)	Follow-up	
	Week –1	Week 0	3 months	12 months
Informed consent	x			
Neurological examination	x	x	x	x
Medical history	x			
Comorbidities	x		x	x
Medication	x	x	x	x
Patient questionnaires				
ODI	x		x	x
Pain VAS (back/leg)	x		x	x
SF-36	x		x	x
EuroQOL5D	x		x	x
PGIC	x		x	x
Adverse events		x	x	x
Length of hospitalisation		x		
Imaging				
Spinal MRI (routine) Spinal CT (routine) Flexion-extension radiographs (routine)	x x x			x x x

ODI, Oswestry Disability Index; PGIC, patients global impression of change; RCT, randomised controlled trial; SF-36, Short Form-36; VAS, visual analogue scale.

OUTCOMES

Primary outcome

The primary outcome measure for PROMISE is health-related quality of life 1 year after intervention according to the ODI V.1.0 (German version) representing an accepted tool to asses functionality in daily life activities.[17–19] Treatment success is defined as reaching improvement of ≥10 points.

Secondary outcomes

Secondary end points are chosen to address aspects of pain (VAS), quality of life ((RAND) SF-36 Health Status Questionnaire V.1.0, EQ-5D-5L V.1.1), impression of change (patients global impression of change V.1.0), length of hospitalisation after intervention (in days), crossover rates, the amount of pain medication and surgery-related AE rates after 12 months.[20–24] German versions of all patient-reported outcome measures (PROMs) are used.

Crossover

In this study, patients are allowed to crossover from the SCS to the fusion group at any time and crossover rates will recorded. In this case, SCS will be explanted beforehand. This helps to analyse the treatment effect of fusion surgery in patients with SCS treatment failure. Crossover from fusion to SCS is possible but will result in exclusion from the study as regular explantation of the screw-rod system is not recommended.

Adverse events

An AE is any untoward medical occurrence in a patient or clinical trial subject administered a medicinal product and which does not necessarily have a causal relationship with this treatment. A serious adverse event (SAE) is defined as an AE that results in death, a life-threatening experience, initial or prolonged hospitalisation, persistent or significant disability or any condition requiring surgical intervention. SAEs will be classified for intensity, outcome, causality and countermeasures according to a predefined protocol. SAEs have to be reported within 12 hours after the SAE becomes known to the coordinating investigator.

Monitored events

A monitored event form is completed whenever it is learnt that a study patient has been lost to follow-up, has crossed over from their treatment group or has withdrawn from the study. Deaths and hospitalisations are immediately reported to the study Principal Investigator, Data and Safety Monitoring Board. To determine whether the event was related to the treatment or the study, the Safety Monitoring Board uses data in the medical record, discharge operative notes or death certificates. All medical complications are monitored throughout the study at all routine follow-ups and are reported to the Safety Monitoring Board. An annual safety report is written and provided to the EC.

Protocol violations

Any deviation from the study protocol is considered a protocol violation. Major protocol violations include: randomisation of an ineligible patient; enrolment in any other spine-related study; subject receiving the wrong treatment; informed consent violations. Minor protocol violations include failure to report a monitored event within 12 hours of learning of it and failure to obtain follow-up data within the specified time intervals. Violations are reviewed monthly.

Study governance and organisation

The Department of Neurosurgery at the University Hospital Augsburg, Germany acts as study coordinating centre. Baseline characteristics, enrolment, treatment and follow-up data are collected at the participating centres by the local investigator or via self-reporting under supervision of the local investigator using paper CRF. The investigator records the participation in a special identification list of patients. This patient identification list gives the possibility to a later identification of the patients and contains the patient number, full name, date of birth and the date of the enrolment in the study. This patient identification list remains in the Investigator Site File (ISF) at the Clinical Trial Centre after the closure of the study.

Data and safety monitoring

Monitoring visits to the study sites will be made periodically during the study to ensure that all aspects of the protocol are followed. In addition, each centre will be visited by the monitor before trial start and after study site closure. Monitoring will follow standard operating procedures. Source data verification will be performed for key variables that are specified in the Monitoring Manual. In total, about 20% of all data have to be monitored completely. Domestic regulatory authorities, the EC and an auditor authorised by the Chief Investigator may request access to all source documents, CRFs and other study documentation for on-site audit or inspection.

Data management

Data are administered and processed by the data manager from the study coordinating centre at the University Hospital Augsburg. Evaluation of the data takes place by programmed range, validity and consistency checks. In addition, a manual/visual evaluation of plausibility in accordance with the requirements of good clinical practice is performed. Queries may occur, which will be forwarded to the appropriate Clinical Trial Centre. These queries have to be returned to data management, where the discrepancies will be corrected accordingly in the database. After entry of all collected data and clarification of all queries, the database will be closed at the completion of the study.

Patient and public involvement

The research question was designed to answer which of both established therapy options offers the better outcome and/or AE profile to the patient. Patients/

Advisors were not directly involved in the study design and will not be involved in the recruitment or conduct of the study. The results will be published in a peer-reviewed medical journal, the information will be given to individual patients on request.

STATISTICS

Sample size calculation

Sample size was determined for the primary end point, using the ODI scores (means and SD) published by Brox *et al*.[5] For the comparison of proportions of treatment success between both groups, using a continuity corrected χ^2 test on a two-sided level of significance of α=0.05, a sample size calculation was realisable assuming log-normal distribution (nQuery Software V.7.0). As reported by Brox *et al*,[5] 50% of patients had an improvement of ≥10 points in ODI score after 1 year following posterior fusion procedures in patients with low back pain after previous surgery for disc herniation. Referring to the previous study results, a coefficient of variation (SD divided by mean ODI) of about 0.5 can be expected within the treatment groups to be compared. Assuming that 80% of patients in the SCS group have a 10-point improvement in the ODI score, a sample size of 72 patients is needed to observe a significant difference between both treatment groups with a power of >80% in a superiority trial. Sample size estimation was conducted using the Sealed Envelope 2012. Power calculator for binary outcome non-inferiority trial. (Online) Available from: https://www.sealedenvelope.com/power/binary-noninferior/ (accessed 6 June 2016). Assuming a drop-out rate of 15%, a total of 84 patients have to be allocated to the trial.

Statistical analysis

The primary analysis will follow the intention-to-treat (ITT) principle. All randomised patients with a complete preliminary examination will be considered in the ITT population.

Further sensitivity analyses will be provided to evaluate robustness of the results in regard to unexpected circumstances (eg, impact of 'crossover' patients who are not treated as randomised but are required to be analysed as randomised (ITT principle)).

Secondary end points will be analysed in an exploratory manner at a two-sided 0.05 level of significance. Due to an expectable skewed (log-normal) distribution of ODI, raw ODI values will be logarithmised within the primary efficacy analysis. To account for (random) differences in ODI baseline values and to obtain a more precise estimation of treatment effect, an analysis of covariance (ANCOVA) including (logarithmised) ODI baseline score, decompression and centre as adjustment covariables and intervention group as two-level factor variable will be used to compare treatment groups in regard to (logarithmised) ODI-level 1-year postintervention (dependent variable). In this term, evaluation of the adjusted group contrast regarding ODI-level 2-year postintervention (proof of efficacy) will be performed two-sided at a 0.05 level of significance. Due to the assumed log-normal distribution, the exponential function of the model-based group contrast can be interpreted as a n-fold difference in ODI-level 2-year postintervention between the treatment groups. Measurements about the course of follow-up will be analysed by ANCOVA or generalised model alternatives for categorical or semi-quantitative data. Within these analyses, development of data values within the treatment groups about time as well as differences between groups will be simultaneously assessed. The χ^2 test will be used to evaluate differences in overall success rate between the groups. Questionnaires and patient satisfaction index will be analysed as appropriate in dependence on the data distribution. Detailed descriptive statistics will be provided for the data collected and 95% CIs will be calculated for all relevant estimates.

Analysis of safety parameters

Safety and tolerability parameters will be analysed descriptively. Frequencies will be compared by χ^2 and Fisher's exact tests, respectively. Analysis of time-dependent probabilities of critical events will be performed using the Kaplan-Meier method. Furthermore, multivariable event analyses will be performed using Cox proportional hazard regression models.

Handling of missing data

The last observation carried forward approach will be employed in order to perform an ITT analysis of the primary efficacy end point in consideration of all randomised patients. Additionally, for purpose of a supportive sensitivity analysis, multiple imputation procedures will be applied.

Interim analysis

No interim analysis will be performed. Study analysis is conducted after completion of visit 4 (12 months) and final analysis of all study data after termination of the clinical trial. Results will be discussed in the clinical trial report.

DISCUSSION

Study rationale

Sufficient treatment of PSPS2 is still hard to achieve and clear guidelines are lacking.[2] The reasons for this could be multifactorial, that is, patient-dependent, operative or postoperative factors. It affects approximately 20%–40% of patients after spinal surgery.[3 4] Most patients experience significant disability and severe neuropathic pain, which necessitates further, sometimes multiple treatments.[3] Repeat surgeries do not necessarily provide improvements in symptoms. Various surgical procedures such as open surgical, minimally invasive decompression/fusion and neuromodulation, in medical therapy resistant cases, have been suggested as possible management options.[25] However, there is no clear consensus which one to prefer.

Fusion surgery has been applied, hypothesising this might reduce microinstability and irritation in previously operated segments and therefore calm the nerve irritation.[5] In PSPS2, a clear biomechanical dysfunction or neural compression is often lacking. Therefore, decompression and fusion seem less adequate compared with neuromodulation, which has been proven efficacy in conditions with back or leg pain.[7] Furthermore, subjective outcome parameters such as VAS or other PROMs have become increasingly important in judgement of treatment success apart from mechanical aspects of spinal disease.[26 27] This study aims to compare the accepted treatment strategies in a randomised fashion to fill the gap in evidence-based therapy of PSPS2. Gathering and summarising information in course of this study will potentially allow for stratification of the patients suitable for either spinal decompression/fusion or neuromodulatory procedures.

Persistent spine pain syndrome type 2

PSPS2 is a condition whose pathophysiology to date is still not fully understood.[3 28 29] The main symptom is invalidating pain affecting the patient's quality of life. Therefore, research both needs to focus on a better understanding of this syndrome and pragmatically address the main symptom, for example, pain control. Both therapies used in this study are possible approaches to treat PSPS2, even though they are thought to act differently on the possibly underlying pathophysiology (see 'Discussion'/'Interventions' sections).[5 7] The main objective of this study is not to further clarify the pathophysiology of PSPS2, even though the results of this investigation on treatment efficacy might help to draw conclusions on which aspect to address predominantly. As the PSPS2 is a chronic pain syndrome, factors such as psychiatric comorbidities, affective state, microstructural neuroinflammation, biomechanical considerations, central as well as peripheral neuroplasticity and the quality of life, social and familiar circumstances come into play. This trial aims to address the pathology from a pragmatic treatment perspective, comparing two different, but accepted treatment strategies in a real-life cohort and therefore controlling for some but not all possible confounders. At this moment, there is a lack of high-level evidence to guide decision making in the treatment of PSPS2, especially comparing surgical options.[3]

Interventions

In this study, two interventions are compared according to their functional outcome in PSPS2. Both interventions address different pathophysiological mechanisms thought to contribute to pain in PSPS2. Furthermore, both interventions differ substantially in their surgical procedure and invasiveness.[30–33]

Lumbar fusion surgery is considered a standard but more invasive procedure. In this study, fusion surgery includes one or multilevel fusion, with ventral (eg, 360°) or dorsal instrumentation only (with or without posterolateral fusion) and different stabilisation devices according to the treating physician's individual decision. Nevertheless, patients undergoing semi-rigid stabilisation or experimental treatments are excluded. This heterogeneity in treatment has clearly to be addressed as flaw but reflects real-world conditions as fusion can be achieved via various devices and individual fusion strategy has to be adapted to the individual and previously operated patients' spine.

SCS follows another rational than fusion surgery, addressing pain in PSPS2 via orthodromic and antidromic neuromodulation.[7 31–35] It is a technique approved for radicular pain and low back pain as well as complex regional pain syndrome (CRPS).[7 36] Different devices offering distinct patterns of stimulation (frequency, current waveforms, etc) exist on the market.[7 37] Therefore, other than in the fusion group, neuromodulation will be performed using exclusively one device (WaveWriter Alpha) in order to allow for all patients, the same range of neuromodulation settings.[38] Within this range, the optimal neuromodulation settings are free of choice and will be determined by the treating physician and a pain nurse together with the patient.

SCS is a two-staged procedure, considered minimal invasive, resulting in minor blood loss, smaller soft tissue trauma which can be performed in local anaesthesia. Lumbar fusion surgery is more invasive and can be regarded as definite treatment with an explantation rarely performed, mostly in case of infection of nonfusion. The different nature of either procedure, apart from the different functioning might play a role in the postoperative outcome and recovery and will be analysed as well.

Limitations

PSPS2 is a condition influenced by multiple factors, without a clear biomechanical or neurobiological expression.[3] Therefore, the study population is heterogenous and might be refractory to treatment for various reasons. We try to address this by excluding patients with severe psychiatric or systemic comorbidities. Despite narrowing our study population, heterogeneity remains a clear limitation of the study. Neuromodulation treatment with SCS does regularly show constant benefits if treatment is successful, while on the other hand ongoing spinal degeneration might cause additional pain on a pre-existing PSPS2. With a follow-up period of 12 months, some cases of adjacent segment disease or implant loosening will not be displayed but fusion should be achieved after 12 months.

There is no strict regulation for the fusion procedure in this protocol, which might raise the question of technical intercentre differences, with respect to invasiveness or biomechanical concepts. Still, a narrowly standardised study procedure might not properly address the individual anatomy of each patient with PSPS2. With respect to the concept of improvement of functional outcome by lumbar fusion surgery to treat PSPS2, the goal of fusion

can be achieved using different but not a single operative technique.

ETHICS AND DISSEMINATION

In this prospective randomised multicentre trial, we aim to investigate the efficacy of either SCS or spinal fusion surgery in patients with PSPS2 according to functional parameters. We use PROMs such as ODI, EuroQol5D or VAS as well as radiographic studies over a period of 12 months. Data and adverse events will be monitored. Further analysis will be performed to stratify for subgroups and identify optimal candidates to either therapy.

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