

Synopsis

Pedicle screw placement is a key component in spinal procedures such as fusions, deformity correction, and fracture repair. Accurate screw positioning is critical for spinal stability and to avoid complications like neural or vascular injury. Misplacement is a leading cause of early reoperations.

Traditional freehand techniques vary in accuracy, while navigation and robotic-assisted systems offer enhanced accuracy. Robotic systems may also support minimally invasive approaches and improve surgical planning and workflow. Despite promising early results, evidence remains limited regarding their impact on outcomes and cost-effectiveness. Accordingly, “Medicintekniska produktrådet, Sveriges Kommuner och Landsting” (“Medical Devices Products council, Swedish Association for Local Authorities and Regions”) has advised against their routine use in Sweden.

This multicenter, observational non-randomized study includes patients of all ages undergoing surgery with pedicle screws for a spinal disorder. The intervention group receives robotic-assisted screw placement, while controls undergo non-robotic-assisted (freehand or navigation-assisted) surgery. Outcomes include accuracy, surgery time, reoperations, complications, patient-reported outcomes, precision, hospital stay, and cost-effectiveness. All hospitals performing spine surgery in Sweden will participate.

The study has three main objectives, studied in three separate substudies: To study screw placement accuracy, learning curve, and reoperations.

The following protocol is based on the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) checklist [1].

1. Title

ROBOTICSS – Robotic-Assisted Pedicle Screw Placement in Spine Surgery: A Multicenter Prospective Observational Study
Date: 2025-12-01.

2. Trial Registration

This study will be registered at clinicaltrials.gov after approval of the Swedish Ethical Review Authority, which was received 2026-02-02.

3. Protocol Version

1.01.

4. Funding

The study is currently unfunded. Funding will be applied for. Treatment is part of standard clinical care and does not require funding. Funding will be needed to monitor, oversee data collection, analyze data and finalize reports.

5. Roles and Responsibilities

Principal Investigators: Paul Gerdhem and Freyr Gauti Sigmundsson

Co-investigators: Anders Joelsson, Lukas Bobinski, Nikos Schizas, Catharina Parai, Anastasios Charalampidis, Ludvig Vavruch, Ted Eneqvist, Håkan Löfgren, Tobias Kyrk, Erik Vestberg, Kardo Raouf.

Collaborating Institutions: Uppsala University, Uppsala University Hospital, Örebro University, Örebro University Hospital, Umeå University, Umeå University Hospital, Karolinska Institutet, Karolinska University Hospital, Södersjukhuset, Gothenburg University, Sahlgrenska University Hospital, Linköping University, Linköping University Hospital, Lund University, Skåne University Hospital, Länssjukhuset Ryhov, Jönköping county, Länssjukhuset Kalmar, Kalmar.

Study coordinators: Catharina Strömstedt, and others to be appointed.

Roles and responsibilities for each investigator and study coordinator.

All investigators are responsible for study introduction, and to oversee data collection, and arrange any necessary hospital permits.

6. Background and Rationale

Surgical techniques have continuously evolved, with advances enabling more precise and effective interventions. A cornerstone in addressing spinal instability or deformity is pedicle screw fixation—widely used in procedures for deformities, fractures, and degenerative conditions requiring stabilization.

Achieving high accuracy in pedicle screw placement is critical. Misplaced screws can lead to complications such as neural injury, vascular damage, implant loosening, and instrumentation failure—often necessitating revision surgery [2]. Accuracy is therefore essential to reduce risks and improve outcomes.

Improvements such as intraoperative fluoroscopy and advanced navigation have enhanced screw placement accuracy while reducing the need for extensive anatomical exposure. This shift toward minimally invasive surgery has reduced surgical trauma and recovery time, supporting a broader trend toward optimizing patient outcomes through smaller incisions and improved techniques [3].

Robotic-assisted surgery (RAS) represents a further step in this evolution. These systems, which use a navigated robotic arm to assist screw placement, aim to enhance accuracy and reduce variability—which may be especially beneficial for less experienced surgeons. RAS may also streamline intraoperative workflow and support minimally invasive approaches. While early results are promising, there remains limited evidence on the broader clinical benefits, especially during the early learning phase of implementation [4]. Robotic-assisted spine surgery is not sanctioned by the Swedish Association of Authorities and Regions, unless performed in clinical trials.

This study aims to evaluate the clinical introduction of robotic systems in spine surgery, focusing on their impact on reoperations, screw placement accuracy, complications, outcome, and intraoperative workflow.

7. Objectives

This study has three main objectives, analysed in three different substudies: To study screw placement accuracy, learning curve, and reoperations.

Secondary Objectives: To assess complications, patient-reported outcomes, length of stay, surgical time, and cost-effectiveness.

8. Trial Design

Multicenter, non-randomized observational cohort study with consecutive patient inclusion.

9. Study Setting

All hospitals in Sweden performing spinal surgery will participate.

10. Eligibility Criteria

Inclusion Criteria:

- Treatment with pedicle screws in the cervical, thoracic, lumbar spine and/or sacrum.
- All ages and spinal diagnoses

Exclusion Criteria:

- Treatment without pedicle screws

Consent

-All patients will be treated according to each hospital's routine. Patient consent will therefore not be needed.

11. Interventions

Experimental Group: Robotic-assisted pedicle screw insertion using available equipment. Currently available systems are Brainlab Cirq and Mazor Robotics, but others systems may be used.

Control Group: Patients undergoing non-robotic-assisted (freehand or navigation-assisted) pedicle screw placement.

12. Outcomes

Primary objectives and outcomes

Substudy 1 primary outcome - Screw placement accuracy (binary per-patient outcome)

- Proportion of patients in which at least one screw is not accurately placed.

Substudy 2 primary outcome- Learning curve (surgical time)

-To evaluate when time in surgery is no longer decreasing in robotic-assisted surgery.

Substudy 3 primary outcome - Reoperation rate at 2 years

-The primary outcome is the occurrence of reoperations of any cause within 2 years from the index surgery in patients undergoing robotic-assisted surgery compared to non-robotic-assisted (navigation-assisted or free hand) surgery.

Secondary Outcomes

- Intraoperative (screw placement precision, including comparisons preoperative and postoperative positioning for screws and rods, surgical time; skin-to-skin as well as wheel-in wheel-out time, estimated patient radiation exposure, intraoperative bleeding)
- Postoperative outcomes (length of stay, patient-reported outcome measures (PROMs), time to return to work)
- Cost-effectiveness and procedural resource use
- Complications (care related infections, thrombosis, emboli, cardiovascular, mortality)

Table 1

Table over data collection and source.

	Radiographic data	Reoperations	Intraoperative metrics	Postoperative outcomes; complications, PROMs
Data source	PACS	SPOR, Swespine, NPR	SPOR/Surg planning program/Electronic health records	Swespine, SFR, SPOR, Electronic health records
Data origin	Radiology department	Surgeon, Anesthesiologist, Hospital	Surgeon/Anesthesiologist	Patient
Need for separate assessment	Yes, radiographic assessment by the investigators	No	No	No
Time points for data collection	Preoperative, intraoperative, postoperative, up to 2 years	Postoperative, within 2 years	Intraoperative	Preop and up to 2 years postoperative

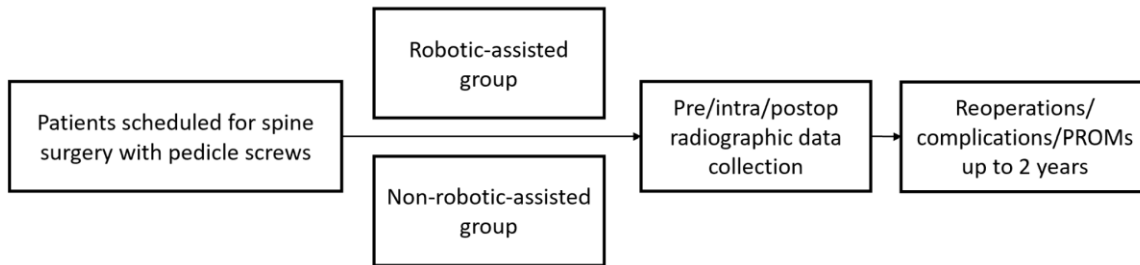
Swespine: Swedish Spine Register

SFR: Swedish Fracture Register

SPOR: Swedish PeriOperative Register

13. Participant Timeline

Figure 1. Participant timeline. Data will be collected up to 5 years postoperative.



14. Sample size

Substudy 1- Primary outcome- Screw placement accuracy (binary per-patient outcome)

Accurate screw placement is defined as a pedicle screw that remains entirely within the cortical boundary of the pedicle, or with up to 2 mm breach of the pedicle wall (corresponds to Gertzbein-Robbins Grade A and B) [5]. To evaluate screw placement accuracy, we will define a binary per-patient outcome: whether at least one screw is not accurately placed.

Based on previous literature, robotic-assisted systems may achieve clinically acceptable accuracy per screw (Gertzbein-Robbins Grade A and B) of approximately 97%, while navigated systems achieve approximately 93% [6], and freehand 84-90% [7, 8].

Assuming a minimum of 4 screws per patient, the estimated probability of at least one non-clinically acceptable screw is 12% in the robotic group and 25% in the navigated and free hand group.

Using a two-sided alpha of 0.05, 80% power, and a 1:6 group ratio, the required sample size is 71 patients in the robotic-assisted surgery group and 426 patients in the non-robotic-assisted surgery group, for a total of 497 patients. We added patients to 75 in the robotic-assisted surgery group, for a total of 501 patients, to be able to include an equal number of patients from Örebro, Umeå and Uppsala. This estimate is conservative, as most patients are expected to receive more than 4 screws, which would increase the likelihood of detecting placement differences.

The primary analysis will use either mixed-effects logistic regression or logistic regression with cluster-robust standard errors to account for intra-patient correlation of screw outcomes.

A secondary analysis of robot-assisted surgeries after the first 501 patients may be performed.

Substudy 2 - Primary outcome - Learning curve (surgical time)

To evaluate the learning curve associated with robotic-assisted surgery, we will model operative time as a function of case number. Operative time is expected to decrease with experience, then plateau. We will use mixed-effects piece-wise linear regression with the surgeon as a random effect to estimate the case number at which operative time levels off. We will look both at wheel-in wheel-out time (primary), and skin-to-skin time (secondary). We expect to do this analysis after each center has performed 100 robot-assisted spine surgeries, in total 300 surgeries.

We have not conducted a traditional power analysis for this substudy, as the objective is not to test a binary hypothesis but to estimate when operative time stabilizes. If no clear inflection point is observed, this will be interpreted as evidence that the learning curve is either very short (already completed), very gradual, or inconsistent. Such a result would itself be informative, and will require us to compare operative times with today's standard of care, navigated or free hand surgery.

Substudy 3- Primary outcome – Reoperation rate at 2 years

The primary outcome is the occurrence of reoperations of any cause within 2 years from the index surgery. The expected reoperation rate in the non-robotic group is likely to be higher than 3-5% over a 2-year period [9–11], and may in the robotic-assisted group be 1% or less [12]. A difference of 2 percentage points or greater is considered clinically meaningful. Power analyses (80% power, α 0.05) have been made in two scenarios, with reoperation rates of 3% vs 1%, or 5% vs 3%. We estimate a ratio of 1:6 for robotic-assisted surgery vs navigation-assisted or free hand surgeries.

Comparing 3% and 1% reoperation rates, 420 robotic-assisted surgery patients and 2,520 non-robotic surgery patients are needed (yielding a total sample size of 2,940 patients). In case reoperation rates are 5% and 3%, 866 robotic-assisted surgery patients and 5,196 non-robotic surgery patients are needed (yielding a total sample size of 6,062 patients). An increased proportion of robotic-assisted surgeries or a larger difference in reoperation rates will decrease the total sample size.

An estimated 1800 patients per year are treated with pedicle screw instrumentation at the hospitals, totaling 7,200 patients in 4 years. If we after 4 years deem that the sample size will not be reached in a reasonable time frame, the study will be stopped.

No patients will be lost to follow-up, as outcomes will be ascertained through linkage with national quality, health and surgical registries, requiring no active participation from patients or clinical teams beyond standard registration. If a patient moves abroad before the 2-year period has come to an end, their existing data will be used.

To reduce confounding by indication in this non-randomized design, we will apply both propensity score matching (PSM) and inverse probability weighting (IPW). The propensity score will be estimated using logistic regression, incorporating relevant baseline covariates including age, sex, BMI, smoking status, diagnosis, number of levels fused, revision status, surgical approach (minimally invasive vs. open), interbody device use, and fixed effects for hospital site.

In the primary analysis, 1:2 nearest-neighbor matching without replacement will be used, with a caliper of 0.2 standard deviations of the logit of the propensity score. Covariate balance after matching will be evaluated using standardized mean differences (SMDs), with $SMD < 0.1$ considered acceptable. Outcome analysis will be performed using Cox proportional hazards regression with robust standard errors to account for matched pairs.

As a secondary analysis, IPW will be used to create a pseudo-population in which treatment assignment is independent of observed covariates. Stabilized weights will be applied, and outcome analysis will be conducted using weighted regression models, adjusted for baseline covariates to enhance robustness.

Although both methods are suitable for dealing with moderate imbalances in group size, it is important to note that reducing the size of the non-robotic group may limit the number of matches available during PSM and could increase variance in the IPW analysis if extreme weights arise. These risks will be mitigated through careful diagnostics, including evaluation of match yield, standardized mean differences, and weight distributions. Overlap weighting or trimming will be considered if weight instability is detected.

While the study is powered at 80% based on the reduced cohort, adjusted analyses using propensity score methods may yield a slightly reduced effective sample size due to matching inefficiency or variance inflation. However, both approaches are expected to preserve sufficient power to detect the prespecified effect size, given the projected event rate and available sample size.

Multiple imputation will be used to handle missing baseline data, and all patients will be included in the final analysis. An increased proportion of robotic surgeries relative to non-robotic surgeries will decrease the overall sample size requirement to detect the same effect.

Secondary outcome - Screw placement precision

We will evaluate screw placement precision as the deviation between preoperative planning and actual placement in robotic-assisted surgery cases. For each screw, linear deviation (at the tip and tail) perpendicular from the planned position, to the actual position, and angular deviation between the planned position and the actual position will be measured. This comparison will be made on an overlay of the preoperative planning made on a preoperative computed tomography, and compared with the computed tomography performed intra- or postoperative for assessment of pedicle screw position.

Stratified comparisons (e.g., by spinal level or surgeon experience) may be performed to identify patterns of deviation. We plan to use the first 60 cases in the study in each of 3 centers that perform robotic-assisted spine surgery for this analysis, and for comparison divide them into a first ($n=30*3$) and second group ($n=30*3$), in all 180 cases.

Other secondary outcomes

Other complications

Thromboembolic, cardiovascular complications and mortality will be assessed as secondary safety outcomes. These events are rare in spine surgery, and although the study is not powered to detect small differences in such outcomes, comparisons between robotic and non-robotic cohorts will be reported.

Other outcomes

Length of stay, time to return to work will be described, but no power calculation has been made.

Health economic analysis

A health economic analysis will be performed and resource use described. No power calculation has been made.

Patient reported outcomes (PROMs)

Patient reported outcomes will be collected through the Swedish Spine Register (Swespine) and the Swedish Fracture Register (SFR). Response rates at 1 year is around 75-80%. Response rates in the SFR are lower. The majority of patients will be registered in Swespine (only fracture patients are registered in the SFR). Depending on diagnoses different questionnaires are used. The only questionnaires in Swespine and SFR that are distributed irrespective of diagnoses are EQ-VAS running from 0 (worst) to 100 (best possible health) and EQ-5D. Other questionnaires are Oswestry Disability Index (ODI), Scoliosis Research Society-22revised (SRS-22r), Early Onset Scoliosis Questionnaire-24 (EOSQ-24) and Short Musculoskeletal Function Assessment (SMFA), but are only answered by subpopulations. Several studies indicate that 2 year data does not result in additional information compared to 1 year data, so our primary analysis will use 1 year data, which are available in both Swespine and SFR.

Continuous outcome analysis

EQ-VAS will be analyzed as a continuous variable. We consider a 5-point difference between groups as clinically relevant at the group level, corresponding to a small-to-moderate effect size (Cohen's d appr. 0.25), with an expected standard deviation of 20 points, power 80% and α

0.05. The minimum required number of answering patients in the robotic-assisted group would be 147 and in the non-robotic-assisted group 882. We will exceed this number and achieve a quite reliable estimate if all patients are included in this analysis, also when considering that 30%-40% may not respond to questionnaires in Swespine and SFR.

PASS (Patient Acceptable Symptom State)

We will report the proportion of patients reaching a Patient Acceptable Symptom State (PASS), defined as EQ-VAS ≥ 75 for elective cases and ≥ 65 for non-elective cases. A PASS threshold of 10 percentage point difference in the proportion achieving PASS is considered meaningful. The minimum required number of answering patients in the robotic-assisted group would be 226 and in the non-robotic-assisted group 1,356 if power is 80% and α 0.05. We expect the sample size to provide sufficient power to detect any difference.

15. Recruitment

Patients will be included consecutively at each site during the enrollment window which is planned to be four years (2025–2029). Currently robotic-assisted spine surgery is available in two hospitals (Umeå and Örebro), with a third hospital waiting for their equipment to be installed (Uppsala). If other hospitals install robotic-assisted surgery during the study period this will just result in more patients involved in the robotic-assisted arm of the trial, which would result in a potentially faster inclusion of the needed amount of patients. We still believe that during the study period more patients will be operated with non-robotic-assisted methods than with robotic-assisted methods.

16–17. Allocation and blinding

No randomization or blinding will be performed. If a planned robotic-assisted surgery is abandoned after the start of surgery, the patient will be included in the robotic-assisted group (i.e. intention to treat principle).

18. Data collection methods

Data will be collected through national registries (Swespine, the Swedish Fracture Register, the Swedish PeriOperative Register, hospital systems (electronic health records, surgical planning software, Picture Archiving and Communication System; PACS and others). PROMs will be recorded preoperatively, and at follow-ups (Swespine: 1, 2 and 5 years; the Swedish Fracture Register: 1 year). Images will be retrieved using standardized CT protocols and assessment will be made by at least two researchers independently.

19. Data management

Data will be collected and managed in compliance with GDPR. Regular validation and updates will occur every 6–12 months. Final datasets will be stored at Uppsala University for a minimum of 15 years.

20. Statistical methods

Statistical analysis will compare outcomes using appropriate parametric or non-parametric tests,

including survival methods. Baseline characteristics will be adjusted for using multivariable models. Adjustment variables include age, diagnosis, comorbidities, previous spine surgery, number of levels, number of screws, robotic system type, use of navigation or free-hand surgery and hospital.

Analysis is currently planned to be performed in R. Interim analyses will be performed when half of the patients have been included. Sensitivity analyses will be performed as described earlier.

21. Data monitoring

If funding is available a formal Data Monitoring Committee will be appointed. All data are collected within the regular health care system which means that the data is subject to regular clinical monitoring as part of standard practice. Reporting of deviations (clinical practice or complications) will be done within regular hospital systems.

22. Harms

Harms will be tracked via registry data and clinical records. These include infections, reoperations, and other adverse events, including mortality.

23. Auditing

Study sites may be subject to independent audits by the hospital, external parts contracted by the hospital or governmental agencies. Records will be maintained in compliance with Good Clinical Practice.

24. Ethics Approval

Ethical approval will be obtained from the Swedish National Ethical Review Authority prior to initiation.

25. Protocol Amendments

All protocol changes will be documented. If protocol changes require submission for ethical approval this will be done prior to implementation, except in urgent safety situations.

26. Consent and confidentiality

Informed consent is not required since all interventions are standard of care. After data extraction and before analyses, all data will be pseudonymized and handled in accordance with national privacy legislation.

27. Declaration of interests

Paul Gerdhem has received lecture fees from DePuySynthes, Johnson and Johnson Medtech (to himself). Gauti Sigmundsson has received lecture fees from DePuySynthes, Johnson and Johnson Medtech (to himself). Lukas Bobinski has received teaching honoraria and a research grant from Medtronic. All other investigators and collaborators declare they have no conflict of interest.

28. Access to data

The research group (investigators and collaborators) will have access to the final dataset.

29. Ancillary and post-trial care

No specific post-trial care beyond standard clinical and national quality and health register-based follow-up is planned.

30. Dissemination policy

The results will be submitted for peer-reviewed publication and presented at scientific conferences. Summary findings will be posted in public trial registries.

31. Use of generative AI

Generative AI (Chat GPT 4o) has been used for assistance in coding the preliminary power analyses and for grammar correction. Power analyses has then independently been recalculated by statistician Jonas Selling at “Statistikakademin”, Uppsala, Sweden.

Figure 2. Study timeline. Years are indicated.

	2025	2026	2027	2028	2029	2030	2031
Ethical application	—						
Clinical trials registration	—						
Study inclusion		—	—	—	—		
Primary outcome - Screw accuracy		—	—	—			
Primary outcome - learning curve		—	—	—			
Primary outcome – Main study-reoperations			—	—	—	—	—
Secondary outcome, placement acc to plan		—	—	—			
Secondary outcome, complications, PROMs			—	—	—	—	—

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