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# Postoperative Outcomes Within Enhanced Recovery After Surgery Protocol in Elective Total Hip and Knee Arthroplasty. POWER.2 Study: Study Protocol for a Prospective, Multicentre, Observational Cohort Study

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**Abstract**

**Objective:** The number of indications for total hip replacement (THR) and total knee replacement (TKR) surgery is increasing. Enhanced recovery after surgery (ERAS) represents the next step in the evolution of standardised care. The primary aim of this study is to measure the in-hospital 30-day medical and surgical postoperative complications rate. The study's secondary aims are to determine the length of stay, 30-day mortality rate, 30-day reoperation and readmission rates, the ERAS overall compliance and predefined ERAS individual items compliance.

**Methods:** This multicentre, prospective, observational study will include adult patients (aged >18 years) undergoing elective THR and TKR surgery. Consecutive patients undergoing surgery within the 2-month data collection period will be included. Centres that offer the THR and/or TKR surgery will be eligible to participate. The data collection will be done through an online data collection form via a secure, password-protected platform at each centre with predefined data fields.

**Results:** Ethical approval for this study has been obtained from the Comité de Ética de la Investigación de la Comunidad Autónoma de Aragón (C.P.-C.I. PI18/135; on 23 May 2018). It was prospectively registered on 27 June 2018, at www.clinicaltrials.gov with identification no. NCT03570944.

**Conclusion:** The study will be disseminated through the SPARN-RedGERM, SEDAR, GERM and through social media. Peer-reviewed publications will be published under corporate authorship, including POWER.2 Study Group and SPARN-RedGERM.

**Keywords:** Arthroplasty, arthroplasty, follow-up studies, hip, knee, outcome and process assessment (health care), replacement

## Introduction

Joint replacement surgery for both the hip and knee is one of the most common elective surgical procedures carried out in Europe and in the United States (1). The number of indications for total hip replacement (THR) and total knee replacement (TKR) surgery is increasing, and a considerable growth in the number of THR and TKR surgical procedures is foreseen during the next decade, which make these surgeries one of the most expensive processes for health services (2). It is increasingly evident that a sustainable model for joint replacement surgery should emphasise value without compromising patient outcomes. Early functional recovery and hospital stay are important for surgeons, patients and health administrators.

THRs and TKRs are associated with a low risk of morbidity and mortality compared to other surgeries. In general, mortality rates after THRs and TKRs are approximately 0.2%, with morbidity rates of approximately 2.9% (2). Enhanced recovery after surgery (ERAS) involves the use of multiple perioperative strategies to facilitate the best conditions for surgery and recovery, in an effort to achieve faster hospital discharge and a rapid resumption of normal activities after surgery, through the reduction of perioperative stress. Although individual components may vary, most ERAS programmes include avoiding prolonged fasting, preoperative optimisation of health (recommendations on diet, alcohol consumption, etc.), preoperative carbohydrate loading, patient blood management, goal-directed haemodynamic therapy, multimodal analgesia with opioid avoidance, early withdrawal of tubes (drains, urinary catheter), support of the gastrointestinal function and mobilisation and early feeding (3).

The ERAS protocols have shown repeatedly that they reduce the length of hospital stay (4, 5) without influencing the rates of complications or readmission in abdominal surgery (4, 5). Despite widespread success in multiple surgical subspecialties, ERAS remains poorly studied and poorly reported in orthopaedic surgery literature. Berend et al. (6) found that adopting a holistic programme of perioperative enhanced recovery reduced inpatient stays and readmissions after THRs and TKRs. However, the authors only reviewed the non-surgical measures and concluded that they can be effective in accelerating recovery. They suggested combining these measures with minimally invasive surgery to achieve the best possible results and a faster recovery (6).

Our objective is to carry out a 60-day state cohort study of patients older than 18 years undergoing elective THRs and TKRs with or without an ERAS programme with any level of compliance with an ERAS protocol (0%-100%) to provide detailed data describing postoperative complications, associated mortality and hospital stay and in addition, to determine if the application of an ERAS programme affects postoperative complications in patients undergoing elective THRs and TKRs and which ERAS individual components have an impact on clinical outcomes.

## Methods

### Study objectives

The primary aim of POWER.2 is to determine the incidence of predefined medical and surgical postoperative complications at 30 days of follow-up after elective THRs and TKRs in centres with or without an ERAS protocol with any level of protocol compliance (from 0% to 100%). The secondary aims of this study are to determine in-hospital mortality, assess the relationship between ERAS compliance and postoperative complications and assess the influence of each of the predefined ERAS items on postoperative complications.

**Study design**
We aim to undertake a prospective, multicentre, observational cohort study of consecutive patients undergoing elective THRs and TKRs.

**Setting**
This study will take place across anesthesiology and orthopaedic surgery units across Spain over a consecutive period of 2 months. Any hospital that offers THRs and/or TKRs will be eligible to participate.

**Recruitment**
All patients undergoing an elective THRs and TKRs in Spanish participating centres will be eligible for the study. Since adherence to the ERAS protocol will be assessed, no potential hospital will be excluded for having or not having an established ERAS protocol, or for the adherence to ERAS.

**Eligibility Criteria**

**Inclusion criteria**
All adult patients (aged >18 years) undergoing an elective THR and TKR surgical procedure will be eligible for this study. Types of approaches for TKRs will include medial parapatellar, midvasto and subvasto (others), with surgical technique of both components cemented, hybrid (not cemented femoral and cemented tibial) or not cemented.

Types of approaches for THRs include posterolateral, anterolateral, lateral direct and direct anterior (other), with surgical technique of both components cemented, hybrid (femoral cemented and acetabular not cemented) or not cemented.

**Exclusion criteria**
Patient refusal, patients undergoing emergency surgery; patients undergoing partial prostheses, protheses revision or replacement surgeries will be excluded from the study.

**Outcome measures**
The primary outcome measure is in-hospital 30-day postoperative complications.

Complications are defined and graded according to the standards for definitions and use of outcomes for clinical effectiveness research in perioperative medicine: European Perioperative Clinical Outcome definitions (7), the standardised list and definitions of the Knee Society (8), the Standardised List, Definitions and the Stratification Developed by the Hip Society (9); and the definition and severity of bleeding results from an adaptation from the standardised bleeding definitions for cardiovascular clinical trials (Supplementay Material, Tables 1-3) (10).

Secondary outcome measures will include the length of stay, 30-day mortality rates, 30-day reoperative and readmission rates, the ERAS overall compliance and ERAS individual items compliance. The level of care after surgery will also be recorded as defined in Table 1. Patient timeline is described in Figure 1.

**Data Collection and Data Management**
Each participating local hospital will be responsible for identifying potentially eligible patients for study recruitment. The principal investigator team will consist at least, but not limited to, a consultant orthopaedic surgeon and/or a consultant anaesthetist. Patients will be identified from three clinical areas-outpatient clinic, preoperative assessment clinic and daily elective operating lists-to ensure all potentially eligible patients are captured.

The data collection will be done through an online data collection form via a secure, password-protected platform at each centre with predefined data fields. All data will be anonymised, so patients cannot be tracked, and all anonymised

| | STUDY PERIOD | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | Enrolment | Day of surgery | Follow-up | | | | | Close-out |
| TIMEPOINT | $-t_1$ | 0 | *Day 1* | *Day 2* | *Day 3* | *Day 4* | *etc.* | *30 day* |
| ENROLMENT: | | | | | | | | |
| Eligibility screen | X | X | | | | | | |
| Informed consent | X | X | | | | | | |
| Inclusion | | X | | | | | | |
| *FOLLOW-UP* | | | ◆ | — | — | — | — | ◆ |
| ASSESSMENTS: | | | | | | | | |
| *Preoperative Variables* | X | | | | | | | |
| *Intraoperative variables* | | X | | | | | | |
| *Postoperative variables and clinical outcomes* | | | X | X | X | X | X | X |

**Figure 1. Schedule of enrolment, interventions and assessments**

**Table 1. Level of care after surgery**

1. Critical care Level 3: Includes advanced organ support, for example, invasive ventilation and renal replacement therapy.

2. Critical care Level 2: May include advanced cardiorespiratory monitoring (e.g. invasive arterial/central venous monitoring) and basic organ support (e.g. non-invasive ventilation and inotropic/vasoactive drug administration).

3. Post-anaesthetic care unit: Care within a designated area for the patients in the immediate recovery from anaesthesia. May deliver care at Levels 1 to 3.

4. Surgical ward (Level 0/1): Normal ward care without Level 2 or 3 capabilities.

The level of care should be defined according to the care the patient received rather than the location. For example, a patient receiving Level 2 care in a Level 3 area should be recorded as receiving Level 2 care.

**Table 2. ERAS compliance definitions (adapted from 3)**

| | ERAS Included Individual Items | Definitions of ERAS Compliance for Included Individual Items |
|---|---|---|
| 1 | Presurgical education | Received verbal and written ERAS education at a dedicated preadmission visit |
| 2 | Presurgical optimisation | Patients stopped smoking 4 weeks before surgery, and alcoholics ceased all alcohol consumption 4 weeks before surgery |
| 3 | Preoperative fasting | Preoperative fasting limited to 2 hours for clear liquids (water, coffee, juice without pulp), and at 6 hours for solids |
| 4 | Patient blood management | Set of measures applied to optimise preoperative haemoglobin, avoid bleeding and avoid transfusion |
| 5 | Preoperative carbohydrate drinks preload | Given preoperative carbohydrate drink. Defined as at least 50 g carbohydrate in at least 400 mL fluid in the form of a dedicated preoperative beverage with a proven safety profile. Given up until 2 hours before anaesthesia |
| 6 | Avoidance of long-acting sedative premedication | No long-acting sedative premedication given (e.g. opioids, sedative antihistamines and neuroleptics) |
| 7 | Thromboprophylaxis | Given thromboprophylaxis; low-molecular-weight heparin and compression stockings |
| 8 | Antibiotic prophylaxis | Given antibiotic prophylaxis before skin incision |
| 9 | Regional anaesthesia | Anaesthetic procedure that allows rapid awakening, adequate analgesia and patient recovery. The item is considered positive provided that any major anaesthetic technique (spinal anaesthesia or general anaesthesia) is accompanied by local or locoregional anaesthesia techniques; or continuous epidural anaesthesia |
| 10 | PONV prophylaxis | Given PONV prophylaxis |
| 11 | Active prevention of unintentional hypothermia | Use of fluid heaters and/or thermal blanket for all patients during the surgical procedure |
| 12 | Goal-directed fluid therapy | Intravenous fluid administration guided by haemodynamic goals based on the cardiac output or derived monitoring by any validated cardiac output monitoring |
| 13 | Postoperative analgesia | A multimodal analgesic management that includes at least two drugs in order to avoid or reduce the administration of morphics |
| 14 | Postoperative glycaemic control | Patients receive glycaemic control in the first 24 hours, for target glycaemia $<180$ g $dL^{-1}$ |
| 15 | Early mobilisation | Defined as the patient move at least to armchair in the first 12 postoperative hours |
| 16 | Early feeding | Defined as the patient tolerates oral feeding in the first six postoperative hours |

ERAS: enhanced recovery after surgery; PONV: postoperative nausea and vomiting

data will be submitted centrally. A list of patients will be used in each centre to match identification codes in the database of individual patients to record the clinical results and provide any data that may be missing. The required anonymous data fields of this data collection form are shown in Tables 2-5 and include demographic, surgery and anaesthesia related variables, Patient Blood Management variables and ERAS individual item compliance. All anonymised data will be subsequently analysed. Outcome data specific to each surgeon or centre who participates in the study will not be analysed.

## Statistical analysis

### Sample size calculation

Our plan is to recruit as many centres as possible on a national basis and ask them to include all eligible patients in the study. Only those centres that include at least 10 valid patients will be included in the final data analysis. Those centres that present a smaller number of patients recruited will be evaluated individually, according to their characteristics to be included in the final analysis. We do not have a specific sample size, and the statistical models will be adapted to the event rate provided by the sample recruited.

However, a minimum sample size is estimated, expecting 50% of patients with at least one complication-which are the data that require a larger sample size-with a confidence level of 95% and an accuracy of 3%, of a total of 3012 patients. The larger the sample size, the more accurate it will be. So, it is intended to recruit the largest possible number of centres and patients.

**Table 3. Explanatory data variables collected for POWER.2**

| Patient | Pharmacological | Surgical | Laboratory |
|---|---|---|---|
| • Age<br>• Gender<br>• BMI<br>• ASA Score<br>• Smoking status<br>• Hypertension<br>• Diabetes mellitus<br>• Coronary arterial disease<br>• Stroke<br>• COPD/Asthma<br>• Atrial fibrillation<br>• Peripherical arterial disease<br>• CHADS2-VASc score<br>• Clinical frailty scale | Anti-aggregants and anticoagulants (type, daily dose and the time at which the drug was withdrawn until surgery) | • Surgery time<br>• Intraoperative blood loss<br>• Intraoperative diuresis<br>• Intraoperative fluid administration (including type of fluid)<br>• Surgical aproach<br>• Surgical technique<br>• Time of ischaemia<br>• Intraoperative fluid balance<br>• Use of surgical drain | • Haemoglobine<br>• Albumin<br>• Creatinine<br>• Glicaemia<br>• Glycosilated haemoglobin<br>• Ferritine<br>• Transferrine Saturation<br>• C-reactive protein<br>• Vit B12 |

BMI: body mass index; ASA: American Society of Anesthesiologists physical status classification;

COPD: chronic obstructive pulmonary disease; CHADS2-VASCs: estimates stroke risk in patients with atrial fibrillation. In all patients, the fluid balance is calculated as follows: administered fluids (including crystalloid, colloid and blood products) − (estimated bleeding + insensible losses* + diuresis) *1.5 mL $kg^{-1}$ $h^{-1}$

**Table 4. Patient blood management variables**

| Preoperative | Intraoperative | Postoperative |
|---|---|---|
| • Preoperative Hb<br>• Preoperative RBC transfusion<br>• Preoperative iron treatment (dose, time, type)<br>• Preoperative epoetin (dose, time, type)<br>• Preoperative Hb after optimisation<br>• Preoperative autodonation | • Tranexamic acid administration (dose, route) (antifibrinolitics)<br>• RBC transfusion<br>• Intraoperative RBC cell saver | • Postoperative Hb<br>• Postoperative iron treatment (dose, time, type)<br>• Postoperative tranexamic acid<br>• Postoperative epoetin (dose, time, type)<br>• Postoperative RBC cell saver |

Hb: haemoglobine; RBC: red blood cell

**Table 5. Analgesia variables**

| | THRs | TKRs |
|---|---|---|
| **General**<br>**Spinal**<br>**Epidural** | | |
| **Regional**<br><br><br><br><br><br>**Periarticular injections**<br>**Peri-incisional** | • Femoral nerve block<br>• Sciatic nerve block<br>• Shutter nerve block<br>• Fascia iliaca block<br>• Lumbar plexus block<br>• Paravertebral block | • Femoral nerve block<br>• Sciatic nerve block<br>• Adductor canal block<br>• Lumbar plexus block<br>• Paravertebral block |

Catheter utilisation will be evaluated for regional anaesthesia techniques (epidural, regional, periarticular and paraincisional)

We will analyse outcomes depending on whether the patient belonged to an ERAS programme as declared by the hospital where the intervention will be performed. The discrete and continuous variables will be described as n (%) and median ($P_{25}$-$P_{75}$) and their differences analysed using the Fisher or Pearson and Wilcoxon tests respectively. Subsequently, we

will repeat the analysis, subdividing the sample into quartiles according to the real compliance rate of the ERAS items, and comparing the quartiles of higher and lower compliance and calculating a linear fit of the compliance with the variable under study. Next, we will analyse the complications rate for each of the ERAS items using the Fisher test and will perform a multivariate analysis to study the influence in the rate of each of the items together with the clinical and demographic variables. Finally, we will apply the Kaplan-Meier test to determinate whether there were differences in-hospital and critical care length of stay depending on the patient's inclusion in an ERAS programme or the ERAS compliance quartile. To avoid errors by multiple comparisons, we will calculate the respective q-value for each p-value to maintain a false discovery rate below 5%. We will admit as statistically significant those comparisons where the p-value and q-value are below 0.05.

Excel 2010 will be used for data handling, and statistical modelling will be conducted in SPSS V.22.

**Methods for minimising bias**

All patients will be consecutively screened, and if found to be eligible, informed consent will be obtained. The number of screened, included and analysed patients will be reported, and differences will be explained.

Preoperative data capturing and outcome assessment will be performed by two different investigators. Statistical analysis will be performed after the database closure.

Statistical measurements such as imputation will be taken to minimise the risk of bias due to incomplete outcome data. The results of this study will be prepared in accordance with guidelines set by the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement for observational studies (11).

To avoid the risk of selective reporting, the trial protocol with full information about oucomes and variables is hereby published. Any financial relationship or any conflict of interest that could inappropriately influence the work within this project will be stated explicitly. Confounding will be minimised by inclusion of covariates and factors in the statistical analysis of the primary end point.

**Additional analyses and data sharing**

We have developed a process for enabling us to consider requests from investigators outside the Steerning Committee to conduct secondary analyses on POWER.2 data. This includes formal consideration by the POWER.2 project team and steering committees using a predefined standard data sharing request form.

**Ethical approval**

Ethical approval for this study has been obtained from the Comité de Ética de la Investigación de la Comunidad Autónoma de Aragón (C.P.-C.I. PI18/135; on 23 May 2018). It was registered on 27 June 2018 at www.clinicaltrials.gov with identification no. NCT03570944. Local ethical approval will be required at each participating centre. Although this study has no impact on clinical practice, informed consent will be requested for all participants. Patient data will be treated in accordance with the European General Data Protection Regulation 2016/679. The study protocol, technical appendix and other documents are available on www.grupogerm.es/power2.

**Project management**

The POWER.2 Steering Committee will be responsible for protocol development, data collection and data analysis. A structured system of regional and local leadership has been created to coordinate the POWER.2 study. Regional leads will recruit, advice and ensure the correct approvals are in place for each hospital within their region. Local leads will oversee data collection in their hospital, ensuring adherence to local governance protocols and continuous data collection.

## Results

**Dissemination**

The protocol will be disseminated through the Spanish Perioperative Audit and Research Network (RedGERM), the Spanish Society of Anaesthesia and Critical Care (SEDAR) and the 'Grupo Español de Rehabilitación Multimodal' (GERM). All protocol documents and relevant clinical toolkits will be made available through the POWER.2 website (www.grupogerm.es/power2). Individual unit data will be presented at local meetings. Overall collective data will be published in peer-reviewed journals. It is anticipated that the results from this prospective study will help inform ongoing clinical research and will be used to inform commissioning and implement changes within the Spanish National Health Service.

## Discussion

Currently, there is no agreed consensus on the optimal perioperative strategy in patients undergoing elective THRs and TKRs. Due to the large differences in the number and nature of the individual elements included in the ERAS programmes, the incomplete information in the studies, the lack of standardisation in the ERAS programmes and the lack of agreement on what constitutes an ERAS protocol, there is little evidence about which specific protocol elements are those that are associated independently with improvements in the postoperative outcome. Although this occurs in other

surgical disciplines, it is especially important in orthopaedic surgery. Overall, a high level of participation is expected at the national level, which is why the data obtained will make it possible to clearly establish the key ERAS elements as well as the patients who will benefit most from the ERAS protocol and, on the other hand, identify those areas in which more research is needed.

Our study is, to the best of our knowledge, novel for investigating current perioperative management in patients undergoing elective THRs and TKRs and its subsequent impact on clinical outcomes with collaborative support from orthopaedic surgeons and anaesthetists. Moreover, we hope to reach a high number of patients included in a very short period of time, which makes the data obtained more reliable. We also will investigate current Patient Blood Management (PBM) programme influences in the ERAS programme. Preoperative anaemia is quite frequent in these patients, and even if mild, it is associated with worse outcomes (12). We will analyse the impact of PBM measures on the improvement of ERAS programme benefits.

## Conclusion

The data generated from this prospective, multicentre and observational cohort study will help to identify and plan future research areas, evaluate the efficacy of ERAS protocols in the elective practice of THRs and TKRs, develop a consensus on appropriate clinical endpoints and accumulate data for the generation of power calculations to develop future randomised controlled trials.

You can reach the supplementary material of this article at https://doi.org/10.5152/TJAR.2019.87523

**Ethics Committee Approval:** Ethics committee approval was received for this study from the research ethics committee of Comunidad Autónoma de Aragón, Spain (C.P.-C.I. PI18/135; on 23 May 2018).

**Informed Consent**: Written informed consent was obtained from patients who participated in this study.

**Peer-review:** Externally peer-reviewed.

**Author Contributions:** Conception and writing of protocol: Javier Ripollés-Melchor. Participation in the collaborators meeting, development of study concept and editing of protocol: Javier Ripollés-Melchor, Ane Abad-Motos, Margarita Logroño-Egea, César Aldecoa, José Antonio García-Erce, Ignacio Jiménez-López, Concepción Cassinello-Ogea, Oliver Marín-Pena, Carlos Ferrando-Ortolá, Rubén Casans-Francés, Ana Mugarra-Llopis, Alejandro Suarez de la Rica, Manuel Gómez-Ríos, Rubén Sánchez-Martín, Alfredo Abad-Gurumeta, Ana Mugarra-Llopis, MarinaVarela-Durán, Javier Longás-Vailén, Álvaro Ramiro-Ruiz, Ana B. Cuellar-Martínez, José M. Ramírez-Rodríguez and José M. Calvo-Vecino. Statistical analysis plan: Rubén Casans-Francés, José M. Calvo-Vecino and Javier Ripollés-Melchor. All authors read and approved the final manuscript.

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