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TRIPLE-BLIND RANDOMIZED CONTROLLED TRIAL PROTOCOL COMPARING INTRAOPERATIVE PERIARTICULAR INJECTION OF STEROIDS *VS.* NO ADMINISTRATION IN PATIENTS UNDERGOING HIP REPLACEMENT

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ABSTRACT – *Objective:* Hip replacement (HR) is a common and successful orthopedic procedure for end-stage osteoarthritis (OA) and other hip diseases, although postoperative pain management remains a critical aspect of HR. In this light, intraoperative periarticular administration of corticosteroids (CS) has been suggested to decrease postoperative pain, reduce the incidence of nausea and vomiting, improve postoperative range of motion, and decrease the systemic inflammatory response, overall reducing hospital stay and improve patient recovery without increasing the risk of complications. However, the available literature lacks comprehensive information on the effectiveness of CS in improving pain management and accelerating functional recovery in HR.

Methods and Analysis: A triple-blinded randomized controlled trial (RCT) was designed to evaluate the efficacy of intraoperative periarticular CS supplementation for HR patients (treatment group) in the immediate postoperative period and up to 2 years of follow-up, compared to the routine perioperative analgesia protocol without CS supplementation (control group). The aim of this trial is to assess the benefit and safety of CS supplementation, with the hypothesis that it provides greater pain improvement in patients undergoing HR. Additionally, several other outcomes will be analyzed: postoperative recovery, length of hospital stay, hip range of motion, time to mobilization, and patient-reported outcome measures (PROMs). Patient satisfaction, postoperative nausea, opioid consumption, inflammatory response, and glycemia will also be evaluated.

Ethics and Dissemination: The Cantonal Ethical Committee of Ticino, Bellinzona, Switzerland, has approved the study protocol. Written informed consent is obtained from all the participants. The findings of this study will be disseminated through peer-reviewed publications and conference presentations.

Conclusions: The results of this study will provide important data to understand the effect of periarticular CS in HR procedures, both in terms of risks and benefits. Moreover, the study findings will clarify if the potential benefits of CS supplementation could extend beyond short-term pain relief, offering longer-lasting advantages for patients undergoing HR.

Protocol version: Version 3 (21 December 2022).

Trial registration number: NCT05023369, ClinicalTrials.gov.

KEYWORDS: Arthroplasty, Corticosteroids, Hip, Injection, Protocol, RCT, Replacement.

INTRODUCTION

Hip replacement (HR) is a common orthopedic prosthetic procedure performed routinely worldwide and is considered one of the most successful treatments for end-stage osteoarthritis (OA) and other hip diseases[1]. Postoperative pain management remains a critical aspect of HR, as patients often require opioid analgesics[2]. Accordingly, there has been significant interest in improving postoperative pain management to reduce patient discomfort, shorten hospital stays, and decrease healthcare costs. In fact, uncontrolled postoperative pain is a predominant adverse outcome of orthopedic surgeries, leading to extended hospital stays, delayed rehabilitation, increased unplanned readmissions, low patient satisfaction, and the potential development of chronic pain syndromes[3,4]. Optimizing analgesia protocols for effective postoperative pain control is essential to expedite recovery, enhance mobilization, and reduce hospitalization duration[5,6].

Traditionally, postoperative pain control also relied on opioids, which are associated with significant adverse effects such as nausea, vomiting, hypotension, sedation, ileus, constipation, and respiratory depression[5,7,8], prompting the research and development of more effective pain management solutions[2]. In this light, evidence from other joint replacement procedures[9-12] suggested that corticosteroids (CS), when added to a multimodal pain regimen, can decrease postoperative pain, reduce the incidence of nausea and vomiting, improve postoperative range of motion, and decrease the systemic inflammatory response. Moreover, these benefits can potentially shorten hospital stays[11,13,14]. For instance, a recent meta-analysis[11] on patients undergoing total knee arthroplasty (TKA) demonstrated the efficacy of CS in reducing postoperative pain without increasing the risk of complications such as local infections.

Despite these overall positive effects and the growing evidence supporting periarticular analgesic injections, the findings reported for TKA may not be directly transferable to HR, and there is still a lack of high-level and well-powered randomized controlled trials (RCT) providing robust evidence on the efficacy of intra- and periarticular CS in patients undergoing this type of procedure. Specifically, the literature lacks comprehensive information on their effectiveness in improving pain management and accelerating functional recovery in HR patients[15,16]. Furthermore, the impact of perioperative CS supplementation on long-term outcomes remains underexplored. Addressing this gap is crucial, as the intensity of acute postoperative pain has been linked to the risk of developing chronic postoperative pain[17,18]. Therefore, the benefits of CS supplementation could extend beyond short-term pain relief, offering longer-lasting advantages for patients undergoing HR.

Objective and Trial Design

A triple-blinded RCT was designed to evaluate the efficacy of periarticular intraoperative CS supplementation for HR patients (treatment group) in the immediate postoperative period and up to 2 years of follow-up, compared to the routine perioperative analgesia protocol without CS supplementation (control group). The trial uses a 1:1 allocation ratio. The primary objective of this trial is to investigate the efficacy of CS supplementation in reducing postoperative pain, with the hypothesis that it provides greater pain improvement in patients undergoing HR. Additionally, as secondary objectives, several other outcomes will be analyzed to assess the possible broader impact of CS supplementation. These include postoperative recovery, length of hospital stay, hip range of motion, time to mobilization, and patient-reported outcome measures (PROMs). Moreover, patient satisfaction, postoperative nausea, opioid consumption, inflammatory response, and glycemia will also be evaluated. Finally, the safety of CS supplementation will be assessed as a separate objective by recording and analyzing all related complications and adverse events.

METHODS AND ANALYSIS

Study Setting

The study is a double-center, triple-blind RCT, with all activities related to the study performed in two sites of the Ente Ospedaliero Cantonale, Lugano and Bellinzona, Switzerland. These are the two main hospitals of the Ticino Canton, and both have the same standard of clinical practice. This trial

protocol is produced according to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) reporting guidelines to ensure maximum study quality and transparency[19]. The trial was registered in ClinicalTrials.gov with registration number NCT05023369.

Eligibility Criteria

Patients are recruited according to the following criteria.

Inclusion criteria:

- Patients undergoing unilateral primary HR.
- Male or female patients between 50 and 90 years old.
- Body mass index between 18.5 and 35 kg/m^2.
- Patients' ability and consent to participate in clinical and radiological follow-up.
- Informed consent documented by signature.

Exclusion criteria:

- Patients undergoing revision surgery.
- Patients with contraindications to CS or non-steroidal anti-inflammatory drugs (NSAIDs).
- Patients with active CS or immunosuppressive therapy in the 30 days before the operation.
- Patients with clinically significant concomitant disease states or with ASA IV classification (e.g., unstable angina, poorly controlled chronic obstructive pulmonary disease (COPD), symptomatic congestive heart failure (CHF), recent myocardial infarction or stroke).
- Patients suffering from uncompensated diabetes mellitus.
- Patients suffering from chronic systemic diseases such as immunodeficiency, autoimmune diseases, gout, or rheumatoid arthritis.
- Known or suspected non-compliant patients or inability to follow the study procedures (e.g., due to language problems, psychological disorders, or dementia).
- Patients abusing alcohol or drugs.
- Patients who participate in another study with investigational drugs.
- Patients already enrolled in this study.
- The patient is the investigator, one of his/her family members, employees or other dependent persons.

Intervention

All patients undergo HR performed by experienced orthopedic surgeons specialized in hip surgeries. The HR procedure is conducted with the patient positioned supine or laterally, depending on the chosen surgical approach. To minimize confounders, spinal loco-regional anesthesia is administered uniformly to all patients. Following sterile preparation and draping, surgical access is meticulously achieved to expose the hip joint. After osteotomy and thorough preparation of the femoral and acetabular components for prosthetic implantation, the surgeon administers an injection into the peri-articular tissues of the hip joint. This is achieved through multiple injections into the peri-capsular tissues, aiming for a homogeneous distribution of the drug all around the joint, regardless of the surgical approach. The anesthesiologist prepares the injection syringe according to the patient's randomization arm. For patients randomized to receive CS administration, a 50 mL syringe containing 9 mg of Dexamethasone is prepared. This is achieved using the commercial product Mephameson, which contains 4 mg of Dexamethasone sodium phosphate per mL, corresponding to 3 mg of Dexamethasone. Thus, 3 mL of Mephameson solution is drawn and mixed with 47 mL of saline solution (NaCl 0.9%) to obtain 50 mL of solution for injection. Conversely, for those randomized to no CS supplementation, the anesthesiologist prepares a 50 mL syringe containing only saline solution (NaCl 0.9%). The blinding of the surgeon is ensured by the fact that the two solutions are visually indistinguishable. Following the injection, prosthetic components are placed, and their alignment and stability are assessed by the surgeon. Wound closure is ensured through layer-by-layer suturing. Postoperatively, in order to limit confounders, a standardized anesthesia protocol is followed for all patients, consisting of Paracetamol 1 g four times a day, Ibuprofen 400 mg three times a day, and, if needed, Morphine 5 mg subcutaneously max 6 times a day. Postoperative CS use is avoided. Patients are typically discharged after three to five days, based on their condition. Weight-bearing on the operated limb with the support of two crutches and physiotherapy begins on the first postoperative day. Thromboembolic prophylaxis and pain control with analgesics, as needed, are prescribed for the first 6 weeks. Patients are instructed to avoid hip flexion over 90 degrees and to limit excessive physical activities during the initial 6-week period.

Outcomes

The primary outcome of the study is the mean postoperative daily pain at rest in the first three days after surgery, assessed with the 0-10 numeric rating scale (NRS). The 0-10 NRS is a valid and reliable instrument for the self-assessment of symptoms, consisting of an 11-point numeric scale, with 0 indicating no pain and 10 reflecting the worst possible pain[20-22].

The secondary outcomes include:

- Mean postoperative nausea during the first three days, evaluated for both incidence and intensity on a 0-10 NRS.
- Mean postoperative hip function during the first three days, assessed on a 0-10 NRS.
- Postoperative hip pain reported on a 0-10 NRS using a questionnaire in the 2-week, 6-week, 3-month, 6-month, 1-year and 2-year follow-ups.
- Quality of life assessed through the European Quality of Life-5 Dimensions-5 Level (EQ-5D-5L) score in the 2-week, 6-week, 3-month, 6-month, 1-year and 2-year follow-ups. The EQ-5D-5L score is a well-known health-related quality of life score, preferred for evaluating cost-utility analysis and changes in general health after surgical operations. It contains 5 questions and ranges from -0.59 (worst) to 1 (best)[23].
- Hip function assessed through the Harris Hip Score in the 2-week, 6-week, 3-month, 6-month, 1-year and 2-year follow-ups. The Harris Hip Score is a standardized assessment of patients following hip arthroplasty, comprising 10 items covering four domains: pain, function, absence of deformity, and range of motion. The score ranges from 0 to 100, with higher scores indicating better outcomes[24].
- PainDETECT assessed in the 6-month, 1-year and 2-year follow-ups. PainDETECT is a patient-reported questionnaire consisting of seven questions addressing the quality of pain symptoms. No physical examination is required. A score of ≤12 indicates that pain is unlikely to have a neuropathic component (<15%), while a score of ≥19 suggests that pain is likely to have a neuropathic component (>90%). An intermediate score (13-18) indicates a possible neuropathic component[25].
- Postoperative opioids and analgesic drugs consumption evaluated with the Medication Quantification Scale (MQS) score at the 6-week follow-up. The MQS score is calculated for each medication by taking a consensus-based detriment weight for a given pharmacologic class and multiplying it by a score for dosage. The obtained values for each medication are then summed for a total MQS score, providing a useful point measure of medication usage for any pain medication regimen[7,8,26].
- Postoperative inflammatory response in terms of hematic C-reactive protein (CRP) and erythrocyte sedimentation rate (ESR) in the first three postoperative days.
- Glycemia in the first three postoperative days.
- Time from surgery to first mobilization.
- Time needed for climbing stairs the first time after surgery.
- Length of hospital stay.
- Safety of periarticular CS supplementation, evaluated in terms of the rate of serious adverse events (SAEs) related to CS supplementation, rate of prosthetic joint infections, wound infections, or healing problems. To delineate a complete safety profile, all SAEs, including those not related to CS supplementation, will be documented until the 6-week follow-up visit.

Recruitment

Patients are recruited at the outpatient clinics of the Ente Ospedaliero Cantonale by properly trained medical staff from the team of orthopedic surgeons in the Department of Orthopedics and Traumatology. When an orthopedic specialist schedules a patient for an HR surgery, enrollment takes place after a careful screening of the eligibility criteria. The study procedures are thoroughly explained to the patient, who freely gives their consent by signing the informed consent form (ICF).

Participant Timeline

After the ICF is signed during the screening visit, the patient and the surgeon, in coordination with research assistants, complete the relevant questionnaires. Follow-up assessments are performed on the first three postoperative days, at discharge, and then at 2 weeks, 6 weeks, 3 months, 6 months, 1 year, and 2 years postoperatively. Each follow-up includes a physical examination, various ques-

tionnaires and outcomes evaluation as previously described. Data are collected using the previously mentioned dedicated study forms and are securely stored and inserted into an online institutional database for the purpose of the present study. Patient enrollment began in May 2022, and the trial is currently ongoing. Recruitment is expected to be concluded by the end of 2025, with all 2-year follow-ups completed by the end of 2027. The detailed participant timeline is outlined in Table 1.

Blinding

This is a triple-blind RCT, with participants, outcome-assessing physicians, and surgeons all blinded to treatment allocation. Only the anesthesiologists involved in the surgery and preparing the syringe with or without CS will be aware of the group to which the patient is assigned, but they will not participate in the follow-up visits. If the outcome-assessing physicians inadvertently become aware of a patient's group allocation, they are required to report the matter and will no longer participate in subsequent follow-up visits for that patient. Another properly trained physician will take over the follow-up assessments for the specified patient.

The blinding of treated patients is further ensured by the fact that the planned surgery does not change based on the study arm to which the patient is allocated. Imaging evaluations are conducted by experienced radiologists, who are also blinded to the type of treatment that the patients have received and the evaluation timing. Unblinding of all necessary personnel will be possible in case of adverse events requiring it. If unnecessary, patients, the assessor and all the study team members will remain blinded. Patients will be informed about their randomization arm at the end of the study or in case of suspension or premature study termination.

Allocation

A total of 110 eligible patients are randomly allocated in a 1:1 ratio (55 patients per group) to receive either intra-articular CS supplementation, concomitant to their HR, or no supplementation. The allocation is based on a computer-generated sequence. Research staff members dedicated to study organization and monitoring, but with no direct involvement in the study procedures, conduct the allocation of the enrolled patients. The randomization list is password-protected and accessible only to staff members not directly involved in the study.

Adverse Events and Assessment Process

Adverse events (AEs) are monitored both intraoperatively and at every follow-up. Safety and efficacy are monitored at the follow-ups, during which patients are asked to spontaneously report any AEs. Adverse events are documented in the patient case report form (CRF). SAEs are defined as those resulting in death or those life-threatening, requiring hospitalization or intervention to prevent permanent damage (in accordance with the requirements of the EC).

All AEs are documented at every follow-up visit, and a safety report is submitted once a year to the local EC. In the event of an SAE, it is reported within 24 hours to the study's Sponsor-Investigator. The Sponsor-Investigator reviews the SAE and provides a specific form back to the investigation site. Any SAE resulting in death is reported to the EC within seven days.

To ensure the high-quality execution of the trial in accordance with the protocol, the trial staff receives training from the chief investigators and is provided with details of standard operating procedures and all necessary study material.

Data Collection Methods and Management

Research-trained orthopedic residents (blinded) collect data on paper-based CRFs. Subsequently, trained data analysts process the data into electronic forms. X-rays are stored at the Ente Ospedaliero Cantonale. Surgeons electronically collect the respective operative data shortly after surgery. Study data are stored in a password-protected spreadsheet on a server hosted at the Ente Ospedaliero Cantonale. Only dedicated research personnel have access to the database.

Table 1. Participant timeline.

Study periods	Screening	Surgery	Discharge	Follow-ups					
Visit	**V0**	**V1**	**V2**	**V3**	**V4**	**V5**	**V6**	**V7**	**V8**
Time	**≥2 w before V1**	**0**	**5 d ± 2 d**	**2 w ± 2 d**	**6 w ± 1 w**	**3 m ± 1 w**	**6 m ± 2 w**	**1 y ± 1 m**	**2 y ± 1 m**
Informed consent form	x								
Demographics	x								
Medical history	x		x	x	x	x	x	x	x
In-/Exclusion criteria	x								
Physical examination	x		x	x	x	x	x	x	x
Vital signs	x	x							
Laboratory tests	x								
X-ray examination	x		x		x			x	x
Hip ROM	x		x	x	x	x	x	x	x
NRS Pain	x	x		x	x	x	x	x	x
EQ-5D-5L	x			x	x	x	x	x	x
Harris Hip Score	x			x	x	x	x	x	x
PainDETECT	x						x	x	x
Randomisation		x							
Surgery		x							
Steroid supplementation		x*							
NRS nausea		x							
NRS function		x							
CRP, ESR	x	x							
Glycemia		x							
MQS Score	x	x			x				
Time to first mobilization			x						
Tim to first stairs climb			x						
Length of stay			x						
Patient satisfaction				x	x	x	x	x	x
Treatment-related AE		x	x	x	x	x	x	x	
SAEs		x	x	x	x				

AE: Adverse Event; CRP: C-reactive protein; d: day; ESR: erythrocyte sedimentation rate; MQS: Medication Quantification Score; NRS: Numeric Rating Scale; m: month; ROM: range of motion; SAE: Serious Adverse Event; w: week; y: year; *only if the patient is randomized in the CS supplementation arm.

Statistical Analysis

The study hypothesis is that intraoperative periarticular CS supplementation decreases postoperative pain compared to the routine pain management protocol without increasing, or possibly decreasing, the risk of complications.

A statistician performed a power analysis assuming 90% of power and 5% of probability of type 1 error (alpha=0.05). Based on earlier cohort studies[27], standard deviations (SD) of 17.7 for the CS group and 24.5 for the control group were used. A previously reported minimal clinically important difference (MCID) of 1.41 in postoperative NRS pain score between treatments was considered. Accordingly, 50 patients per group are needed. With an expected 10% loss to follow-up, 110 patients (55 per group) will be included. Quantitative variables will be expressed as means and standard deviations. Non-normally distributed variables will be described using medians and interquartile ranges. The significance of the detected difference between the two groups for continuous variables will be tested using a two-sided *t*-test if normally distributed, otherwise with the Mann-Whitney-U test. Dichotomous variables will be reported as absolute numbers and percentages, with the significance of the detected difference tested using the Chi-square test. In case of deviations from the original statistical plan, the protocol will be amended, and its validity will be evaluated by the Ethics Committee. All the changes will be reported in the final publication report.

Data Monitoring

Specific personnel from the Clinical Trial Unit of the Ente Ospedaliero Cantonale (CTU-EOC), an independent entity separate from the clinic and the medical personnel performing the study procedures, will conduct monitoring activities. While no audit plan is established, all required source documents and trial essential documents will be made available by the Sponsor-Investigator in case of inspections by competent authorities, and any critical issue will be addressed promptly. All involved parties will keep the participant's data strictly confidential.

ETHICS AND DISSEMINATION

Research Ethics Approval

Ethical approval was obtained on 10 December 2021 from the Cantonal Ethical Committee of Ticino settled at the Health Office, Via Orico 5, 6501 Bellinzona, Switzerland (Study Identifier: ORT-ORT-28).

Confidentiality and Access to Data

Data are recorded using CRFs and processed centrally at the Department of Orthopedics and Traumatology, Ospedale Regionale di Lugano, Lugano, Switzerland. Hard copies of CRFs are stored in a secure, locked area with restricted access. Electronic data are stored on password-protected servers and kept strictly confidential. Only members of the research team have access to patient information.

Scientific Relevance and Broader Impact

This study holds significant scientific relevance within the field of hip surgery and postoperative pain management. By evaluating the efficacy of periarticular CS supplementation in HR surgery through a triple-blinded RCT, a crucial gap in the current literature can be addressed. Postoperative pain management remains a critical aspect of HR surgery, with substantial implications for patient recovery, hospital stay duration, and healthcare costs. This investigation aims to provide robust evidence on the effectiveness and safety of this intervention, potentially offering an approach to enhance postoperative pain control while minimizing opioid consumption and associated adverse effects. Moreover, by employing a comprehensive set of outcome measures, including PROMs, functional assessments, and inflammatory markers, this study aims to provide a global understanding of the impact of periarticular CS supplementation on the various aspects of patient recovery. The findings of this study

have the potential to inform clinical practice guidelines, optimize surgical protocols, and ultimately improve outcomes for all patients undergoing HR surgery worldwide.

CONCLUSIONS

The results of this study will provide important data to understand the effect of periarticular CS in HR procedures, both in terms of risks and benefits. Moreover, the study findings will clarify if the potential benefits of CS supplementation could extend beyond short-term pain relief, offering longer-lasting advantages for patients undergoing HR.

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Conflict of Interest:

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Informed Consent:

All patients provide informed consent to participate in this study as per study protocol.

Ethics Approval:

The study was approved on 10 December 2021 by the Cantonal Ethical Committee of Ticino settled at the Health Office, Via Orico 5, 6501 Bellinzona, Switzerland (Study Identifier: ORT-ORT-28).

Authors' Contributions:

All authors contributed to the definition of the study protocol and will participate in its execution, from treatment and follow-up to analysis and dissemination.

AI Disclosure:

No generative AI and AI-assisted technologies were used in the writing process of this manuscript.

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