STUDY PROTOCOL

COVER PAGE

Official Title:
The Role of Dexamethasone in Total Knee Arthroplasty: Effects of Oral and Intravenous Administration on Early Postoperative Pain and Mobilization

Brief Title:
Oral vs Intravenous Dexamethasone in Total Knee Arthroplasty

Acronym:
TKA

Study Type:
Observational

NCT Number:
Not yet assigned

Document Type:
Study Protocol

Protocol Version:
Version 1.0

Document Date:
01 March 2026

Study Site: Istanbul Haseki Training and Research Hospital – Department of Orthopaedics and Traumatology

Study Design

This is a single-center, prospective observational cohort study. Participants are assigned to cohorts based on the routine perioperative dexamethasone protocol of the surgeon they voluntarily choose. No randomization or masking is performed. The time perspective is prospective.

Study Population

Patients aged 50–80 years undergoing elective primary total knee arthroplasty due to advanced knee osteoarthritis will be included. All participants must provide written informed consent.

Inclusion Criteria:

- Age 50–80 years
- ASA I–II
- Primary unilateral TKA
- Ability to provide informed consent

Exclusion Criteria:

- Revision TKA
- Rheumatoid arthritis
- Chronic corticosteroid use
- Uncontrolled diabetes mellitus
- Uncontrolled hypertension
- Active infection or endocrine disorder

Study Groups (3 Cohorts)

- Control Group – Routine perioperative care without dexamethasone.
- Intravenous Group – 8 mg IV preoperatively, 4 mg IV postoperative day 1.
- Oral Group – 8 mg oral preoperatively, 4 mg oral postoperative day 1.

Primary Outcome Measures

- Postoperative pain (VAS (Visual Analog Scale) 0–10, preoperatively and every 6 hours for postoperative 48 hours).

- Functional mobility (TUG (Time Up and Go) test, preoperatively and daily during postoperative 48 hours).
- Knee Range of Motion – Flexion and Extension degrees (preoperatively and daily during the first 2 postoperative days.)

Secondary Outcome Measures

- Postoperative nausea and vomiting (Numeric Rating Scale (NRS) 0–10, measured daily)
- White Blood Cell Count (expressed in $\times 10^3/\mu L$, measured daily)
- C-Reactive Protein Level (expressed in mg/L, measured daily)
- Opioid requirement (Cumulative tramadol dose in mg, first 48 hours).
- Postoperative Glycemic Response (mg/dL, first 48 hours)

Statistical Analysis Plan

Normality will be assessed using Shapiro–Wilk testing. Continuous variables will be compared using ANOVA or Kruskal–Wallis tests. Repeated measures will be analyzed using repeated-measures ANOVA or linear mixed models. Categorical variables will be analyzed using Chi-square or Fisher's exact test. Multivariate regression analysis will adjust for confounders. Statistical significance is defined as $p < 0.05$.

Ethical Considerations

The study is conducted in accordance with the Declaration of Helsinki. Ethics Committee approval has been obtained. Participation is voluntary and does not alter standard clinical management.