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Comparing three ways of using parecoxib for pain relief after total knee arthroplasty

Submission date
12/05/2026

Recruitment status
Recruiting

Registration date
13/05/2026

Overall study status
Ongoing

Last Edited
12/05/2026

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Knee osteoarthritis is a common chronic joint disease that causes pain and difficulty in movement. Total knee arthroplasty (TKA) is an effective treatment for advanced knee osteoarthritis, but postoperative pain management remains a challenge. Parecoxib sodium is a commonly used analgesic. This study aims to compare the effects of three different routes of administration (intravenous, intraarticular, and intraosseous tibial injection) on reducing postoperative opioid consumption and relieving pain, with a particular focus on whether intraosseous injection offers greater advantages.

Who can participate?
Adults aged 50–75 years with knee osteoarthritis scheduled for total knee arthroplasty

What does the study involve?
Participants will be randomly assigned to three groups. The three groups will receive parecoxib sodium (40 mg/20 ml) via the following routes during surgery:
1. Intravenous injection (into a vein)
2. Intra-articular injection (into a joint).
3. Intraosseous (tibial) injection (into the shin bone)
Apart from the different intervention routes, all three groups will receive identical surgical, anesthetic, basic analgesic, and rehabilitation protocols.

What are the possible benefits and risks of participating?
Participants may achieve better postoperative pain control and earlier rehabilitation; the study results may help improve analgesic strategies for future patients.
Parecoxib sodium is generally well tolerated, but mild gastrointestinal discomfort or allergic reactions may occur. In rare cases, bleeding or infection at the injection site may happen. The research team will closely monitor and manage any adverse events.

Where is the study run from?
Luoyang Orthopedic Hospital of Henan Province (Orthopedic Hospital of Henan Province) (China)

When is the study starting and how long is it expected to run for?
May 2026 to October 2027

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
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Study information

Scientific Title
Analgesic effect of intraosseous parecoxib sodium injection during total knee arthroplasty: a single-center, three-arm, randomized controlled trial

Study objectives
This study aims to determine whether intraosseous (tibial) injection of parecoxib sodium can more effectively reduce postoperative opioid consumption and alleviate postoperative pain after total knee arthroplasty (TKA) compared with conventional intravenous and intra-articular injections.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 10/04/2026, Medical Ethics Committee of Henan Luoyang Orthopedic-Traumatological Hospital (Henan Province Orthopedic Hospital) (No. 82, Qiming South Road, Luoyang, 471002, China; +86 (0)379-63546181; hnslyzgyyllwyh@aliyun.com), ref: 2026ZXKT0001-02

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Parallel

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Patients with knee osteoarthritis who require total knee arthroplasty

Interventions

This study aims to compare the analgesic effects of three different administration routes of parecoxib sodium during total knee arthroplasty (TKA). Except for the specific routes described below, all three groups of participants will receive identical surgical procedures, basic analgesia, rehabilitation protocols, and other perioperative management strategies. The details are as follows:
In each group, the drug is 40 mg of injectable parecoxib sodium (Emeishan Tonghui Pharmaceutical Co., Ltd., specification: 20 mg per vial), diluted to 20 ml with 0.9% normal saline. The specific administration protocols are as follows:
1. Intravenous injection group: Before inflation of the lower extremity tourniquet, an anesthesiologist slowly injects the 20 ml parecoxib dilution through an intravenous line, ensuring the drug enters the systemic circulation before the limb circulation is blocked, thereby achieving systemic distribution.
2. Intraarticular injection group: Before prosthesis implantation, the 20 ml parecoxib dilution is injected with a syringe into multiple pain targets, including the intraarticular space, posterior capsule, attachment points of the medial and lateral collateral ligaments, the insertion of the quadriceps tendon, and the periarticular soft tissues. This allows the drug to remain in the local tissues and exert its analgesic effect while minimizing systemic exposure.
3. Intraosseous injection group: After arthrotomy and full exposure of the proximal tibia, but before the tibial cut, the following steps are performed: in the cancellous bone area approximately 1 cm medial or lateral to the tibial tuberosity, an injection cannula is inserted perpendicularly into the cancellous bone to a depth of about 1.5–2.0 cm. After confirming secure placement, a syringe is connected and the 20 ml parecoxib dilution is slowly injected. Upon needle withdrawal, gentle pressure is applied to the puncture site with bone wax or a gelatin sponge to seal the hole. The drug is then rapidly absorbed through the marrow sinusoids, initially achieving a very high local concentration in the surgical area and subsequently entering the systemic circulation rapidly.

Random sequence generation:
A member of the research team who is not involved in patient recruitment, intervention delivery, or outcome assessment will generate the random allocation sequence using SAS statistical software.

Randomisation scheme:
Stratified block randomisation with a 1:1:1 allocation ratio among the three groups will be used. Because the type of anaesthesia has a substantial impact on postoperative pain in patients undergoing total knee arthroplasty (TKA), anaesthesia type (general anaesthesia versus combined spinal epidural anaesthesia) will be used as a stratification factor to ensure balance between groups regarding this key prognostic factor. Within each stratum, variable block sizes (mixed 3/6/9) will be applied to maintain approximate balance in the number of patients assigned to the three treatment groups (intravenous, intra-articular, and intraosseous) at any timepoint during the study, while preventing the researcher from easily predicting the next allocation.

Allocation concealment:
To ensure strict implementation of randomisation, sequentially numbered, opaque, sealed envelopes will be used for allocation concealment. Each envelope will bear only a sequence number and stratification information (e.g., "GA 001" for general anaesthesia). The treatment group assignment will be written on a card inside the envelope. After patient enrolment and determination of the anaesthesia type, a team member not involved in subsequent treatment or outcome assessment will open the next envelope in sequence for the corresponding stratum and notify the surgical team of the allocation result.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Parecoxib sodium

Primary outcome(s)
1. Postoperative opioid consumption within 24 hours measured using intravenous morphine equivalents (mg) at within 24 hours after surgery

Key secondary outcome(s)
1. Total postoperative opioid consumption measured using intravenous morphine equivalents (mg) at from end of surgery to hospital discharge

2. Time to first rescue opioid analgesia measured using hours from end of surgery to first request at up to hospital discharge

3. Proportion of participants requiring rescue opioid analgesia measured using percentage receiving at least one rescue opioid dose at during hospital stay

4. Resting pain score of operated knee measured using Visual Analogue Scale (VAS, 0-10) at postoperative 3 h, 6 h, 12 h, 24 h, 48 h, 72 h, 7 days, 14 days

5. Pain score during activity of operated knee measured using Visual Analogue Scale (VAS, 0-10) at postoperative 24 h, 48 h, 72 h, 7 days, 14 days

6. Active range of motion of operated knee measured using degrees measured by goniometer at postoperative 24 h, 72 h, 7 days, 14 days

7. Quality of recovery measured using the Quality of Recovery (QOR-15) questionnaire at 24 h, 48 h postoperatively and at hospital discharge

8. Patient satisfaction measured using 0–10 scale at hospital discharge

Completion date
31/10/2027

Eligibility

Key inclusion criteria
1. Patients aged 50–75 years with a primary diagnosis of knee osteoarthritis
2. Patients scheduled for primary, elective, unilateral total knee arthroplasty without clear contraindications to surgery
3. American Society of Anesthesiologists (ASA) physical status classification I–III
4. Willing to participate in the study and able to provide written informed consent

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
50 Years

Upper age limit
75 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Body mass index (BMI) >35 kg/m² or body weight <50 kg
2. Presence of contraindications to parecoxib sodium, including:
2.1. Allergic reactions
2.2. History of gastrointestinal bleeding caused by NSAIDs
2.3. Inflammatory bowel diseases such as Crohn's disease or ulcerative colitis
2.4. Diagnosed coronary heart disease, lower extremity atherosclerosis, or cerebral atherosclerosis
3. Severe cardiac, hepatic, or renal insufficiency:
3.1. Cardiac function: New York Heart Association (NYHA) class III or IV, or acute myocardial infarction within the past 6 months
3.2. Hepatic function: Child-Pugh class B or C
3.3. Renal function: estimated glomerular filtration rate (eGFR) <30 ml/min/1.73 m²
4. Patients with inflammatory arthropathy, such as rheumatoid arthritis or ankylosing spondylitis
5. Local factors that significantly increase surgical complexity, trauma, or operative time (expected operative time >90 minutes), including: prior ipsilateral knee infection, history of complex fracture, previous periarticular osteotomy, massive periarticular bone defect, functional knee stiffness (preoperative maximum range of motion <50°); or severe deformity (varus >20°, valgus >15°, or flexion >20°)
6. Participation in another clinical trial within the past 6 months
7. Any surgical procedure within the past 3 months
8. Presence of cognitive impairment or psychiatric disorder that prevents compliance with study assessments

Date of first enrolment
25/05/2026

Date of final enrolment
31/05/2027

Locations

Countries of recruitment
China

Sponsor information

Organisation
Luoyang Orthopedic-Traumatological Hospital of Henan Province

ROR
https://ror.org/05br7cm44

Funder(s)

Funder type

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available