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Comparing two types of pain relief after knee replacement surgery: local injection versus nerve block

Submission date
22/08/2025

Recruitment status
No longer recruiting

Registration date
25/11/2025

Overall study status
Completed

Last Edited
25/11/2025

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
This study investigates the best way to control pain around knee replacement surgery. Specifically, it compares two approaches used during total knee replacement (TKA): a local infiltrative anesthesia (LIA) given during surgery, and a nerve block of the femoral nerve (FNB). The goal is to find which method or combination provides better short-term pain control, reduces the need for pain medicines after surgery, lowers the amount of bleeding into the knee joint, and improves knee movement in the first five days after operation.

Who can participate?
125 people undergoing a primary total knee replacement for idiopathic knee joint wear-and-tear (osteoarthritis) are eligible. All participants must be adults who meet the surgical criteria and have given informed, written consent to take part in the study. Exclusion criteria include certain chronic inflammatory joint diseases, post-infectious or post-traumatic knee changes, prior major knee surgeries, very high or very low body mass, an allergy to drugs used in the study, or inability to consent.

What does the study involve?
Participants are randomly assigned to one of four groups (25 people in each group). They do not know which group they are in during the study.
Group 1: Control group receiving a placebo. The soft tissues around the knee are injected with 100 ml of saline solution.
Group 2: Intraoperative local infiltrative anesthesia (LIA) using a fixed mixture of medicines injected into several knee areas (see below) during the operation.
Group 3: Femoral nerve block plus a saline injection instead of LIA.
Group 4: Both femoral nerve block and intraoperative LIA.

The LIA mixture (prepared just before surgery in sterile conditions) consists of:
300 mg ropivacaine (a local anesthetic),

1 mg epinephrine (to prolong the effect and reduce bleeding),
20 mg piroxicam (an anti-inflammatory pain reliever),
made up to a total volume of 100 ml with saline.

The injections are given in five targeted areas around the knee to ensure good distribution:
quadriceps tendon area – 5 ml
posterior knee area (posterior capsule) – 40 ml
Hoffa's fat pad – 10 ml
anterior knee capsule – 40 ml
patellar ligament region – 5 ml

The femoral nerve block is performed after the operation by injecting bupivacaine near the femoral nerve below the groin.

What are the possible benefits and risks of participating?
Potential benefits:
Improved pain control after knee replacement.
Reduced need for oral or injected pain medicines.
Less bleeding into the knee joint after surgery.
Improved knee movement in the days after surgery, which may aid rehabilitation.

Potential risks:
All injections and nerve blocks carry typical anesthesia-related risks, such as temporary numbness, weakness, infection, bleeding, or nerve injury (rare).
Any specific risks related to the drugs used (allergic reactions, side effects from local anesthetics, anti-inflammatory medicines) will be monitored.
Postoperative complications applicable to knee replacement (e.g., infection, thrombosis) are monitored as part of standard care.

Where is the study run from?
Department of Orthopaedics and Reumoortopedics, CMKP
SPSK im. Prof. A. Grucy in Otwock, Poland.

When is the study starting and how long is it expected to run for?
May 2022 to April 2024

Who is funding the study?
Centrum Medycznego Kształcenia Podyplomowego (Postgraduate Medical Education Centre; Poland)

Who is the main contact?
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Additional identifiers

Protocol serial number
7/2022

Study information

Scientific Title
Comparative assessment of the clinical and functional efficacy of local infiltration analgesia (LIA) and femoral nerve block (FNB) in primary total knee arthroplasty (TKA). A prospective randomized study

Study objectives
1. Primary aim: To evaluate the analgesic effectiveness of five anesthesia/analgesia strategies by comparing the total amount of additional opioid analgesics required (converted to morphine equivalents) during the five-day postoperative observation.
2. Secondary aim: To compare patient-reported pain using the Visual Analog Scale (VAS) in the four groups over the five-day postoperative period.
3. Secondary aim: To compare knee joint function by assessing range of motion (ROM) across the

five groups during the five-day postoperative period.
4. Secondary aim: To compare postoperative C-reactive protein (CRP) levels between day 3 and day 5 across the five groups.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 12/01/2022, Bioethics Committee at the Postgraduate Medical Education Centre (Schroegera 82, Warsaw, 01-828, Poland; +48 22-56-01-066; komisja.bioetyczna@cmkp.edu.pl), ref: 7/2022

Primary study design
Interventional

Study design
Single-center interventional single-blind randomized controlled trial

Study type(s)
Efficacy, Treatment

Health condition(s) or problem(s) studied
Postoperative pain prevention in patients undergoing total knee arthroplasty

Interventions
Group 1 (Placebo): Perioperative soft tissue around the operated knee was infiltrated with 100 ml of 0.9% saline (placebo) at the same five injection sites as the active groups: 1) quadriceps tendon region (5 ml); 2) posterior knee joint capsule (40 ml); 3) Hoffa's body (10 ml); 4) anterior knee capsule (40 ml); 5) patellar ligament (5 ml). Intraoperative injections administered immediately before implant placement.

Group 2 (Intraoperative Local Infiltration Analgesia, LIA): Intraoperative knee infiltration with a fixed anesthetic mixture of 300 mg ropivacaine (Ropimol, 10 mg/ml), 1 mg epinephrine (Adrenaline WZF 0.1%, 1 mg/ml), and 20 mg piroxicam (Feldene, 20 mg/ml) diluted to a total volume of 100 ml with 0.9% saline. The 100 ml solution was divided into five injections administered directly pre-implantation at the following sites: 1) quadriceps tendon region (5 ml); 2) posterior knee joint capsule (40 ml); 3) Hoffa's body (10 ml); 4) anterior knee capsule (40 ml); 5) patellar ligament (5 ml).

Group 3 (Femoral Nerve Block + Intraoperative Saline Infiltration): A femoral nerve block with bupivacaine was performed under the inguinal ligament after the procedure, combined with intraoperative infiltration using 100 ml of 0.9% saline distributed as above.

Group 4 (Femoral Nerve Block + LIA): Both a femoral nerve block with bupivacaine and intraoperative LIA as described for Group 2 (300 mg ropivacaine + 1 mg epinephrine + 20 mg piroxicam in 100 ml total volume).

Group 5 (Control): Group of patients without any additional intervention.

Randomization: Eligible patients were randomly assigned to one of the five groups (n = 25 per group) by drawing the group number from sealed, opaque plastic packaging, opened only by the

surgeon performing the total knee arthroplasty to determine the assigned intervention for each patient.

Blinding: Patients were unaware of their group assignment throughout the study. The report does not specify blinding of the clinicians administering the interventions.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Total amount of additional opioid analgesics required (converted to morphine equivalents) during the five-day postoperative observation measured using patient records

Key secondary outcome(s)
1. Pain using the Visual Analog Scale (VAS) in the five groups over the five-day postoperative period
2. Knee joint function by assessing range of motion (ROM) across the four groups during the five-day postoperative period
3. Postoperative C-reactive protein (CRP) levels between day 3 and day 5 across the four groups

Completion date
30/04/2024

Eligibility

Key inclusion criteria
1. Patients scheduled for primary total knee arthroplasty (TKA) due to idiopathic degenerative changes of the knee.
2. Kellgren–Lawrence grade II–III degeneration in the affected knee.
3. Written informed consent provided after comprehensive explanation of the study procedures and aims.
4. Eligibility to receive the specified prosthesis (PS Triathlon, Stryker) as part of the planned TKA procedure.
5. Age range: 60-90 years old

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
60 Years

Upper age limit
90 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Secondary degenerative changes due to chronic inflammatory diseases (e.g., rheumatoid arthritis, psoriatic arthritis)
2. Degenerative changes of post-infectious or post-traumatic origin
3. Prior surgeries around the knee (e.g., peri-knee osteotomies)
Candidates for knee revision arthroplasty
4. Requirement for simultaneous correction of large axial deformities (varus/valgus): valgus > 15°, varus > 10°
5. Massive preoperative motion disorders: flexion contracture > 10°, extension contracture < 80°
5. BMI < 18.5 kg/m² or > 35 kg/m²
6. Allergy to any drugs used in the study
7. Failure to sign informed consent
8. Intraoperative complications (e.g., ligament injuries, peri-prosthetic fractures, common peroneal nerve palsy)
9. Early postoperative complications (e.g., deep vein thrombosis, pulmonary embolism, early prosthetic infection)

Date of first enrolment
19/05/2022

Date of final enrolment
07/04/2024

Locations

Countries of recruitment
Poland

Study participating centre
Prof. Adam Gruca Independent Public Clinical Hospital Postgraduate Medical Education Centre
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Sponsor information

Organisation
Centrum Medycznego Kształcenia Podyplomowego

Funder(s)

Funder type
University/education

Funder Name
Centrum Medycznego Kształcenia Podyplomowego

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be available upon request from MD Maciej Kocon, mail maciej.kocon@cmkp.edu.pl

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			29/08/2025	No	Yes