

Study on the effect of ultrasound-guided nerve block on sleep quality after hip replacement in elderly patients on the basis of patient-controlled analgesia

Submission date 21/10/2026	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 23/10/2026	Overall study status Ongoing	☐ Statistical analysis plan ☐ Results
Last Edited 22/10/2026	Condition category Surgery	☐ Individual participant data ☒ Record updated in last year

Plain English summary of protocol

Background and study aims

Hip replacement surgery is common in older people, but pain after surgery is often poorly controlled. Poorly treated pain makes it hard to start moving again and is linked with sleep problems, delirium, blood clots in the legs and heart and lung complications. Studies suggest that 60% to 80% of older orthopedic patients have moderate-to-severe sleep disruption in the first week after surgery, and pain and lack of sleep make each other worse. The usual pain relief after surgery is opioid-based patient-controlled intravenous analgesia, which can suppress breathing, disturb sleep and cause nausea and vomiting. This study tests whether adding an ultrasound-guided nerve block in the groin (fascia iliaca compartment block), which numbs the nerves supplying the front of the hip, to standard patient-controlled pain relief improves sleep quality after surgery, reduces pain at rest, lowers the body's inflammatory response and reduces the amount of opioid medicine needed, without increasing side effects.

Who can participate?

Men and women aged 60 to 80 years who are scheduled for planned (elective) hip replacement surgery on one hip, are classified as American Society of Anesthesiologists grade II or III, are alert and able to complete the postoperative questionnaires, have a preoperative sleep quality score of 6 or above, and give written informed consent. People who cannot take part include those with infection or major abnormality at the injection site, allergy to amide-type local anesthetics, severe bleeding disorders, uncontrolled severe heart failure, a heart attack in the last 6 months, severe chronic obstructive pulmonary disease, major cognitive or psychiatric problems, long-term use of opioid or benzodiazepine medicines, or severe liver or kidney disease.

What does the study involve?

Participants are allocated by chance (1:1) to one of two groups. Before the general anesthetic starts, the nerve block group receives an ultrasound-guided injection of 30 mL of 0.375% ropivacaine into the space between the fascia iliaca and the iliopsoas muscle in the groin; the other group has a sham (simulated) procedure with ultrasound scanning of the skin and a needle

touching, but not entering, the skin. Both groups then have the same operation under general anesthesia and the same patient-controlled intravenous analgesia pump for 48 hours (after which oral painkillers are given). Neither the participants nor the nurses who assess them are told which group they are in. Over the first three days after surgery, nurses record pain at rest and sleep quality using short questionnaires, blood samples are taken before surgery and 24 hours after surgery to measure inflammation, and any side effects over the first 72 hours are recorded.

What are the possible benefits and risks of participating?

Possible benefits are better sleep in the first days after surgery, less pain at rest, less need for opioid painkillers and a smaller inflammatory response; in this study the nerve block group needed about 43% less intraoperative opioid and reported better sleep, and no serious adverse events occurred. Possible risks include the usual risks of nerve block injection (bleeding, infection at the injection site, or, rarely, local anesthetic toxicity) and the side effects of painkillers, such as nausea and vomiting, dizziness, constipation, itching and slowed breathing; in this study the frequency of these side effects was low and similar in both groups, and no serious events such as local anesthetic toxicity, infection at the puncture site or significant respiratory depression occurred.

Where is the study run from?

Bengbu First People's Hospital, China.

When is the study starting and how long is it expected to run for?

The study as a whole runs from March 2024 to November 2026. Each individual participant takes part from before their surgery until 72 hours after surgery.

Who is funding the study?

Investigator initiated and funded.

Who is the main contact?

Xuebing Shi, shixuebing_sxb212@163.com

Contact information

Type(s)

Public, Scientific, Principal investigator

Contact name

Dr Xuebing Shi

ORCID ID

<https://orcid.org/0009-0007-7375-1218>

Contact details

No. 229, Tuoshan Road, Yuhui District, Bengbu

Anhui

China

233000

+86 19005520358

shixuebing_sxb212@163.com

Additional identifiers

Study information

Scientific Title

Effect of ultrasound-guided fascia iliaca compartment block combined with patient-controlled intravenous analgesia on postoperative sleep quality in elderly patients undergoing total hip arthroplasty: a prospective randomized controlled trial

Study objectives

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 26/03/2024, Bengbu First People's Hospital (No. 229, Tuoshan Road, Yuhui District, Bengbu, Anhui, 233000, China; +86 552 383 8341; wuxiayujie@163.com), ref: BBYY2024005

Primary study design

Interventional

Allocation

Randomized controlled trial

Masking

Blinded (masking used)

Control

Placebo

Assignment

Parallel

Purpose

Treatment

Study type(s)

Health condition(s) or problem(s) studied

Postoperative pain and sleep disorders in elderly patients undergoing total hip arthroplasty

Interventions

All participants receive standardized general anesthesia: after standard preoperative fasting (solids 6 hours, clear liquids 2 hours) and routine monitoring (electrocardiography, blood pressure, oxygen saturation), anesthesia is induced with propofol 1.5–2.0 mg/kg, sufentanil 0.3–0.5 µg/kg and rocuronium 0.5–0.6 mg/kg, and is maintained with 1.0%–2.0% sevoflurane plus target-controlled infusion of remifentanyl, with the bispectral index kept at 40–60 and mean arterial pressure within $\pm 20\%$ of baseline; core temperature is maintained at 36.0°C–37.0°C with a forced-air warming blanket.

Participants allocated to the experimental group receive ultrasound-guided fascia iliaca compartment block combined with patient-controlled intravenous analgesia. Prior to general anesthesia induction, with the patient supine, a 6–13 MHz high-frequency linear array probe is placed transversely approximately 2 cm above the inguinal ligament; using an in-plane technique with an 80–100 mm 22G block needle advanced to the fascial plane between the fascia iliaca and the iliopsoas muscle, 2–3 mL of 0.9% saline is injected for hydrodissection and, after visualization of the “lifting sign,” 30 mL of 0.375% ropivacaine is administered slowly in aliquots under real-time ultrasound observation, with repeated aspiration and at least 30 minutes of vital-sign monitoring after block completion.

Participants allocated to the control group receive patient-controlled intravenous analgesia alone with a sham procedure: at the corresponding time point, the same operator places a sterile ultrasound probe on the skin over the area above the inguinal ligament with coupling gel for 5–8 minutes of simulated scanning, then lightly touches the puncture-site skin with a sterile syringe needle without penetration; no nerve block puncture and no local anesthetic injection are performed. All other anesthesia induction, maintenance and intraoperative management are identical to those in the experimental group.

In both groups, after transfer to the post-anesthesia care unit and once full consciousness has returned with a Ramsay sedation score ≤ 2 , an electronic patient-controlled intravenous analgesia pump is connected using an identical solution (sufentanil 2.0 $\mu\text{g/kg}$ plus flurbiprofen axetil 250 mg diluted with 0.9% saline to 120 mL), with a continuous infusion rate of 2 mL/hour, a bolus volume of 1.0 mL and a lockout interval of 15 minutes; the pump runs continuously for 48 hours and is then removed, after which oral multimodal analgesia (celecoxib 200 mg twice daily combined with tramadol 50 mg every 8 hours as needed) is given.

Participants are randomized 1:1 using stratified block randomization with American Society of Anesthesiologists class (II/III) and age group ($<70/\geq 70$ years) as stratification variables and a block size of 4; allocations are concealed in identical, opaque, consecutively numbered sealed envelopes held by an independent archivist and opened sequentially by a research nurse after written informed consent is obtained.

Intervention Type

Mixed

Primary outcome(s)

1. Resting pain intensity (resting Visual Analog Scale score) measured using a 10-centimetre visual analog scale, where 0 represents no discomfort and 10 indicates the most severe pain conceivable; assessed and recorded by a blinded assessment nurse (test-retest reliability intraclass correlation coefficient = 0.97) at 08:00 (± 30 minutes) on postoperative days 1, 2 and 3

2. Postoperative sleep quality (Richards-Campbell Sleep Questionnaire score) measured using the Richards-Campbell Sleep Questionnaire, comprising 5 dimensions (depth of sleep, latency to sleep, number of awakenings, ease of returning to sleep, and overall sleep quality), each rated on a 100-mm visual analog scale (0 = worst, 100 = best); the final score (range 0–100) is the average of the five dimensions (internal consistency Cronbach's $\alpha = 0.90$) at 08:00 (± 30 minutes) on postoperative days 1, 2 and 3 (time points identical to those for the visual analog scale)

Key secondary outcome(s)

Completion date

30/11/2026

Eligibility

Key inclusion criteria

1. Individuals between the ages of 60 and 80, irrespective of gender
2. American Society of Anesthesiologists (ASA) physical status classification II to III
3. Scheduled for elective unilateral THA, with indications including traumatic (eg, femoral neck fracture) and non-traumatic etiologies (eg, osteoarthritis, avascular necrosis of the femoral head)
4. Clear consciousness with adequate cognitive capacity to understand and complete postoperative scale assessments (VAS, RCSQ, Ramsay)
5. written informed consent after being fully informed
6. An initial Pittsburgh Sleep Quality Index (PSQI) evaluation yielding a score of 6 or above, suggestive of sleep disturbances prior to surgery

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

60 Years

Upper age limit

80 Years

Sex

All

Total final enrolment

60

Key exclusion criteria

1. Local infection at the puncture site, severe anatomical abnormalities, or a history of ipsilateral inguinal nerve block
2. Known allergy to amide-type local anesthetics, or severe coagulation dysfunction (INR >1.5 or platelet count $<80 \times 10^9/L$)
3. Uncontrolled cardiac insufficiency (New York Heart Association Class IV), history of myocardial infarction within the preceding 6 months, or severe chronic obstructive pulmonary disease
4. Significant cognitive dysfunction, a history of mental health conditions, or prolonged use of opioids or benzodiazepines
5. Significant liver or kidney impairment (elevated alanine aminotransferase or aspartate aminotransferase exceeding twice the normal upper range, or an estimated glomerular filtration rate below 30 mL/min/1.73 m²)

Date of first enrolment

05/11/2024

Date of final enrolment

22/01/2026

Locations

Countries of recruitment

China

Sponsor information

Organisation

Bengbu First People's Hospital

Funder(s)

Funder type

Funder Name

Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Xuebing Shi, Email: shixuebing_sxb212@163.com

IPD sharing plan summary

Available on request