ISRCTN17431025 https://doi.org/10.1186/ISRCTN17431025

Comparative analysis of pain control methods after ankle fracture surgery with a peripheral nerve block

Submission date
12/07/2023

Recruitment status
No longer recruiting

Registration date
13/07/2023

Overall study status
Completed

Last Edited
06/08/2024

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
This study aimed to compare the effectiveness of peripheral nerve block combined with dexamethasone/epinephrine versus patient-controlled analgesia using ketorolac in patients with ankle fractures. The rationale for this study was that the analgesic effect of anesthetics could potentially be enhanced by the addition of dexamethasone or epinephrine, although the exact mechanism is still unknown.

Who can participate?
Patients aged 18–70 years who were surgically treated for ankle fractures between December 2021 and September 2022

What does the study involve?
The patients were divided into two groups: Group A received patient-controlled analgesia following lower extremity peripheral nerve block, while Group B received a combination of dexamethasone/epinephrine with the anesthetic solution during peripheral nerve block.

What are the possible benefits and risks of participating?
If a significant pain relief effect was found in this study, it would be an opportunity to relieve pain and increase satisfaction after surgery for subjects who underwent open reduction and metal fixation for ankle fractures.
This study is a prospective interventional study, but it is a drug that is commonly used postoperatively or has already secured safety to reduce postoperative pain, and there are no risk factors that deviate from general treatment for patients due to participation in this study.

Where is the study run from?
Chungnam National University Hospital (South Korea)

When is the study starting and how long is it expected to run for?
November 2021 to October 2022

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Prof. Gisoo Lee, gslee1899@gmail.com

Contact information

Type(s)
Scientific

Contact name
Prof Gisoo Lee

ORCID ID
http://orcid.org/0000-0002-4085-5674

Contact details
4717 Glenwood ave
La crescenta
United States of America
91214
+1 8186534891
gs1899@cnuh.co.kr

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Comparative analysis of pain control methods after ankle fracture surgery with a peripheral nerve block: A single center randomized controlled prospective study

Study objectives
We hypothesized that peripheral nerve block with dexamethasone and epinephrine is more effective than other pain control methods after conventional peripheral nerve block. This study

aimed to prospectively compare peripheral nerve block combined with dexamethasone /epinephrine and patient-controlled analgesia using ketorolac after peripheral nerve block anesthesia in patients with ankle fractures.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 01/12/2021, Chungnam National University Sejong Hospital (Bodeum 7ro, 20, Sejong, 30099, Korea, South; +82 44 995 4950; cnuhirb@cnuh.co.kr), ref: CNUSH 2021-11-003

Study design
Single-center randomized controlled prospective study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital, Medical and other records

Study type(s)
Treatment, Efficacy

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet.

Health condition(s) or problem(s) studied
Ankle fracture

Interventions
All patients were anesthetized using ultrasound-guided PNB with ropivacaine. Group A received PCA with ketorolac for postoperative pain management after PNB. Group B received PCA with normal saline; instead, dexamethasone and epinephrine were added to ropivacaine during PNB. The allocation sequence was concealed from the researchers and participants in sequentially numbered, opaque sealed envelopes. The envelopes were opened only for the researchers after the enrolled participants had completed all baseline assessments when it was time to perform the intervention in the operation room. A sample size of 59 patients was determined based on the following parameters: significance level (5%), statistical power (90%), sample ratio (1:1), variance (2.5), and difference between the two groups (1.5). To obtain a 1:1 ratio between groups, we included 60 cases (30 in each group).
In group A, PCA was initiated approximately 10 hours after PNB induction. The treatment comprised 4 mL ketorolac (120 mg) and 100 mL normal saline. An initial bolus of 8 mL was injected, followed by an additional 96 mL slowly administered by a PCA instrument (Auto Selector; Tecnica Scientifica Service, Torino, Italy) over 48 hours. A maintenance dose of 2 mL /hour was administered, with each additional PCA bolus containing 1 mL and a lockout interval of 15 minutes.
In group B, PNB was performed using an anesthetic solution of ropivacaine (Naropin®,

AstraZeneca AB, Sodertalje, Sweden) combined with dexamethasone disodium phosphate 5 mg (5 mg/mL, Daewon Pharm. Co., Ltd., Seoul, Korea) and epinephrine 0.1 mg (1 mg/mL, Daihan Pharm. Co., Ltd., Seoul, Korea; epinephrine was added at a ratio of 1:200,000). The same PCA instrument was also used for all patients in group B. However, only normal saline was administered in the same way as in group A. We kept all patients unaware of which group they belonged to until the end of the study. To do so, the same PCA instrument was applied to all patients included in this study. In both groups, patients with visual analog scale (VAS) scores ≥5 received intravenous acetaminophen (Kabi paracetamol 100 mL, 1 mg/mL, Fresenius Kabi, Friedberg, Germany) for rescue analgesia. VAS scores obtained within 8 hours of intravenous acetaminophen injection were excluded from the analysis. No other pain control medications or methods were used in either group.
This study was conducted while patients were hospitalized for 3 days after surgery.

Intervention Type
Procedure/Surgery

Primary outcome measure
Pain intensity (VAS score: 0, no pain; 10, worst pain imaginable) at 6, 12, 18, 24, 32, 40, 48, and 60 hours after peripheral nerve block

Secondary outcome measures
1. The time at which the sensation began (analgesia time) and the time at which motor function was restored were recorded using patient records
2. After three days of administering pain control, a questionnaire was completed to assess patients' satisfaction with the pain control method (Likert scale).

Overall study start date
01/11/2021

Completion date
30/10/2022

Eligibility

Key inclusion criteria
1. Unilateral open reduction and internal fixation for ankle fractures were performed on the patients
2. Fracture types included fractures involving the articular surface of the distal tibia and fibula, including simple fibula fractures, bimalleolar fractures, trimalleolar fractures, and pilon fractures.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit

70 Years

Sex
Both

Target number of participants
60

Total final enrolment
60

Key exclusion criteria
1. uncontrolled diabetes mellitus
2. peripheral vascular disease, renal or hepatic disease, or any neurologic disease
3. contraindication for regional anesthesia (coagulopathy or injection site infection).
4. Patients with body mass index <18.5 kg/m² (World Health Organization standard)
5. Patients with suspected or nerve injuries requiring careful post-operative observation and those at risk of compartment syndrome

Date of first enrolment
01/12/2021

Date of final enrolment
30/09/2022

Locations

Countries of recruitment
Korea, South

Study participating centre
Sejong Chungnam National University Hospital
Bodeum 7ro, 20
sejong
Korea, South
30099

Sponsor information

Organisation
Chungnam National University Hospital

Sponsor details
Bodeum 7ro, 20
sejong

Korea, South
30099
+82 1040173308
cnuhirb@cnuh.co.kr

Sponsor type
Hospital/treatment centre

Website
https://www.cnush.co.kr/main/index.do

ROR
https://ror.org/04353mq94

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
30/10/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analyzed during the current study will be available upon request from Gisoo Lee, gslee1899@gmail.com

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		14/07/2023	06/08/2024	Yes	No