


# BMJ Open Effects of pericapsular nerve group (PENG) block on postoperative recovery in elderly patients with hip fracture: study protocol for a randomised, parallel controlled, double-blind trial

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## ABSTRACT

**Introduction** Hip fracture is a common and serious emergency in the elderly, and it is associated with severe pain, significant morbidity and mortality. The use of peripheral nerve block can relieve pain effectively and reduce opioid requirements, which may accelerate patient's recovery. The pericapsular nerve group (PENG) block has been found to provide an effective blockade to the hip joint with a potential motor-sparing effect, so we hypothesised that the PENG block may be an effective tool to enhance the recovery in elderly patients after hip fracture surgery.

**Methods and analysis** This study is a single-centred, randomised, parallel controlled, double-blind trial. A total of 92 elderly patients scheduled for hip fracture surgery will be divided into two groups at random to receive either ultrasound-guided femoral nerve block or ultrasound-guided PENG block. The primary outcome will be to compare the Quality of Recovery-15 scores at 24 hours postoperatively between the two groups. The secondary outcomes will include measuring and comparing the strength of the quadriceps, the visual analogue scale at rest and on movement, the total morphine consumption, the rescue analgesic, the first time of postoperative out-of-bed mobilisation and complications.

**Ethics and dissemination** This study was approved by the Institutional Review Board of the Ethics Committee of The First Affiliated Hospital of Guangzhou University of Chinese Medicine on 15 December 2020 (reference K2020-110). The results of this study will be published in peer-reviewed international journals.

**Trial registration number** ChiCTR2100042341.

## INTRODUCTION

Hip fracture is one of the most serious medical emergencies in the elderly patients, associated with high morbidity and mortality.<sup>1</sup> Surgery has been the generally accepted treatments for hip fracture.<sup>2</sup> However, the overwhelming pain after hip fracture surgery<sup>3</sup> can significantly increase both postoperative complications and mortality, which utterly delay the postsurgical recovery.<sup>4</sup>

## Strengths and limitations of this study

- This study was done to investigate the effects of pericapsular nerve group block on the quality of recovery in elderly patients after hip fracture surgery.
- The primary outcome is Quality of Recovery-15, which can assess multiple domains of recovery.
- Both objective and subjective quality of recovery in the postoperative 24 hours are included.
- A limitation of this study is that Quality of Recovery-15 score could be influenced by delirium, which is a common complication in elderly patients with hip fracture.
- Though objective and subjective outcomes are recorded, measurements are incomplete. For example, some level of neuroinflammatory markers could be the evaluation of recovery.

Therefore, proper analgesics has been identified as a major priority in the management of hip fracture.<sup>2</sup>

In elderly patients, peripheral nerve blocks are effective analgesia techniques with fewer side effects.<sup>5</sup> Compared with traditional intravenous opioids during the initial postoperative period, a multimodal pathway featuring a peripheral nerve block can improve control of dynamic pain, accelerate mobilisation and reduce the opioid-related adverse effects, which may result in fewer complications and improved perioperative outcomes after major orthopaedic surgery.<sup>6-8</sup>

Among peripheral nerve block techniques for dealing with hip fracture, ultrasound-guided femoral nerve (FN) block, fascia iliac compartment (FIC) block and 3-in-1 FN block are widely used. However, the obturator nerve (ON) and the accessory ON (AON) have often failed to exhibit adequate blockade from these blocks,

the effectiveness of these blocks is only moderate accompanied by decreasing the strength of quadriceps.<sup>9–11</sup>

In 2018, Girón-Arango *et al* found out a new regional technique for hip fractures: ultrasound-guided pericapsular nerve group (PENG) block.<sup>12</sup> They concluded that this technique could provide an effective blockade to the articular branches of FN, ON and AON, with a potential motor-sparing effect. Many studies indicated that the PENG block could provide sufficient analgesia with no to minimal opioid requirements at postoperative 24 hours.<sup>13–15</sup> A study showed that the patients receiving PENG block experienced better postoperative pain relief coupled with quadriceps strength improvement compared with those receiving FN block.<sup>16</sup> Encouraged by this outcome, we hypothesise that PENG block may provide a better recovery for hip fractures, especially in the elderly patients. Therefore, this randomised, parallel controlled, double-blind trial is set to compare the Quality of Recovery-15 (QoR-15) scores at 24 hours postoperatively between two groups to investigate whether PENG block enhances recovery in elderly patients after hip fracture surgery.

## METHODS AND ANALYSIS

### Primary aims

The primary aim of this trial is to investigate whether PENG block effectively enhances recovery in elderly patients after hip fracture surgery.

### Secondary aims

The secondary aims are to investigate whether PENG block results in a motor-sparing effect, a reduction in pain score at rest and on movement, a decrease in total morphine consumption and the rescue analgesic, an improvement in the first time of postoperative out-of-bed mobilisation and a decrease in complications.

### Trial design

This is a single-centred, randomised, parallel controlled, double-blind trial. The study will be conducted at The First Affiliated Hospital of Guangzhou University of Chinese Medicine and has been registered with the Chinese Clinical Trial Registry. The methods and results of this study will be reported according to the Standard Protocol Items: Recommendations for Interventional Trials and 2013 statement.<sup>17</sup> The flow diagram for this trial is presented in [figure 1](#).

### Eligibility criteria

#### Recruitment

Elderly patients ( $\geq 65$  years old) with hip fracture who are selected for hip surgery at The First Affiliated Hospital of Guangzhou University of Chinese Medicine will be recruited for this study. Inclusion was initiated in March 2021. The expected study completion date is March 2023.

#### Inclusion criteria

Patients will be included if they: (1) are cognitively intact; (2) have an American Society of Anesthesiologists physical status

(ASA) between I and III and (3) have a body mass index (BMI) between 18 kg/m<sup>2</sup> and 30 kg/m<sup>2</sup>.

### Exclusion criteria

Patients will be excluded if they: (1) refuse to participate in the study; (2) have an allergy or contraindication to the drug or anaesthetic technique in this study; (3) have dementia; (4) have multiple traumas; (5) have severe deafness and vision problems, communication difficulties; (6) have an infection near the block site; (7) are obese (BMI  $>30$  kg/m<sup>2</sup>) or (8) have clinically significant neurological, cardiovascular, renal or hepatic disease (ASA IV–V).

### Informed consent

According to the inclusion and exclusion criteria, patients will be assessed by members of the research team the day before the surgery. Once patients are eligible, researchers will fully explain the study, including the implications, known adverse effects, any risks in taking part and constraints of the protocol, to the eligible patients and their families and answer any questions. If patients agree to enrol, written informed consent will be obtained from the participants and their proxies. Participants can choose to withdraw from the trial at any time and for any reason. Permission will be obtained from each patient regarding the use of their data for statistical analysis.

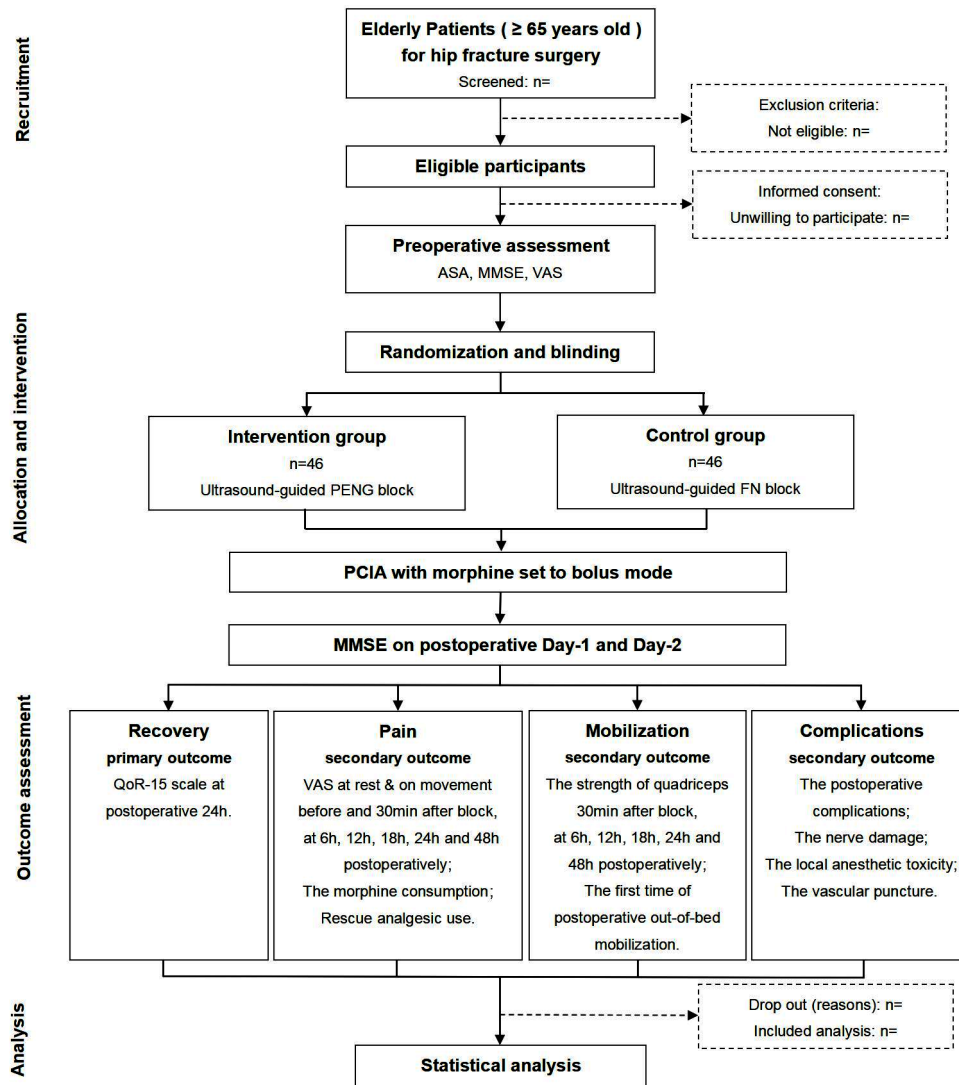
### Preoperative management

In accordance with national guideline,<sup>2</sup> patients in both groups will be receiving standard care to accelerate recovery. The pathway includes rapid assessment from the emergency department, adequate pain control, assessment of bone health and falls, multidisciplinary management, surgical procedures and mobilisation strategies. The ASA status classification will be evaluated, and preoperative cognitive assessment will be performed by using the mini-mental state examination (MMSE).<sup>18</sup> Opioid use will be avoided except for severe pain. Patients who participate in this study will also avoid the use of premedication.

### Intraoperative management

After entering the operating room, continuous ECG, non-invasive intermittent blood pressure and pulse oxygen saturation will be monitored. The patients will be given 4 L/min of oxygen through a mask. In order to reduce any pain or anxiety during the nerve blockade, 0.5 µg/kg of fentanyl will be given intravenously.

The blockade for both groups will be performed by the same experienced anaesthesiologist. Before local anaesthesia, the anaesthesiologist will obtain the sequence from a sealed envelope and perform the blockade according to the allocated information. The anaesthesia for the surgery will be performed after the block and will be managed by a second anaesthesiologist. For both groups, spinal anaesthesia will be chosen as the main anaesthetic technique and will be provided with 0.5% bupivacaine 1.2 mL to 1.8 mL (6 mg to 9 mg) at the L3–L4 interspace, and the sensory block will be controlled at T8–T10.



**Figure 1** The flow diagram for this trial. ASA, American Society of Anesthesiologists class; FN, femoral nerve; MMSE: mini-mental state examination; PCIA, patient controlled intravenous analgesia; PENG, pericapsular nerve group; QoR-15, Quality of Recovery-15; VAS, visual analogue scale.

### Ultrasound-guided PENG block

With patients in a supine position, PENG block will be performed as described by Girón-Arango *et al.*<sup>12</sup> The anterior inferior iliac spine, the femoral artery, the pectineus muscle, the iliopubic eminence, the iliopsoas muscle and tendon will be observed using a curvilinear low-frequency ultrasound probe. The puncture site will be set 0.5–1.0 cm away from the lateral of the ultrasound probe. After 2 mL of 1% lidocaine is injected for local anaesthesia, a 22-gauge, 80 mm needle will be inserted carefully in an in-plane approach from lateral to inner. After the tip of the needle is placed the musculofascial plane between the tendon of the psoas muscle anteriorly and the pubic ramus posteriorly, which is between the iliopubic eminence and anterior inferior iliac spine,<sup>19 20</sup> 1 mL of 0.9% saline solution will be injected to ensure that the solution will be spread in the plane beneath the iliopsoas muscle. After negative aspiration, a total volume of 20 mL of 0.375% ropivacaine will be slowly injected every 5 mL. The spread of the ropivacaine is in the musculofascial plane towards the

iliopubic eminence with the iliopsoas tendon lifted up.<sup>19</sup> The ultrasound view of the fluid spread in the plane will be observed to ensure that the ropivacaine is injected right in the targeted location.

### Ultrasound-guided FN block

With the patients in a supine position, FN block will be performed as described by Marhofer *et al.*<sup>21</sup> A linear high-frequency probe will be used to visualise the femoral artery and the FN. The puncture site will be set 0.5–1.0 cm away from the lateral of the ultrasound probe. After 2 mL of 1% lidocaine is injected for local anaesthesia, a 22-gauge, 80 mm needle will be inserted carefully in an in-plane approach from lateral to inner. After the tip of the needle is placed next to the FN, a total volume of 20 mL of 0.375% ropivacaine will be slowly injected after negative aspiration every 5 mL. The ultrasound view of the fluid spread will be observed to ensure that the ropivacaine is injected around the FN.

### Postoperative management and follow-up

After surgery, when participants are transferred to the ward, vital signs (heart rate, non-invasive blood pressure, pulse oxygen saturation and respiratory rate) will be monitored. Over the course of postoperative 48 hours, a patient-controlled intravenous analgesia (PCIA) with morphine will be started when the operation concludes and set to the bolus only mode (bolus 1.0 mg, lockout 6 min, maximum dosage 15 mg/4 hour). All participants will receive 1 g paracetamol every 6 hour as a part of postoperative multimodal analgesia. In case of nausea or vomiting, 5 mg of tropisetron will be intravenously injected.

### Outcome measurement

Before a series of clinical-scale evaluations and analgesia are evaluated and recorded by an estimator, who is blinded to the group assignments, patients will first be tested with the MMSE on postoperative day 1 and day 2.

The primary outcome measurement of this study will be the QoR-15 scores answered by patients at 24 hours postoperatively.<sup>22, 23</sup> The questionnaire contains 15 items concerning the patient's quality of recovery. Each item is scored on an 11-point scale ranging from 0 to 10, with a total possible score of up to 150 points. The mean value and SD will be used for descriptive analysis.

The secondary outcomes will include the strength of the quadriceps, the visual analogue scale (VAS) of both resting and dynamic pain, the total morphine consumption, the rescue analgesic, the first time of postoperative out-of-bed mobilisation and any complications. To test the strength of quadriceps, patients will be asked to extend the knee of the affected limb while supporting the knee under the popliteal fossa 30 min after the blockade, and at 6 hours, 12 hours, 18 hours, 24 hours and 48 hours postoperatively. The quadriceps strength will be graded to a 6-point scale: 5, normal strength; 4, extension against gravity and light resistance; 3, extension against gravity; 2, extension against gravity eliminated; 1, muscle twitch; 0, paralysis.<sup>24</sup> At the time before and 30 min after the blockade, and at 6 hours, 12 hours, 18 hours, 24 hours and 48 hours postoperatively, the pain scores at rest and on movement will be assessed, respectively. After patients have been resting in bed for 15 min, VAS at rest will be assessed. When VAS on movement is assessed, participants will be asked to perform the operative hip flexion to 45°. Using an 11-point numerical rating scale, the VAS ranges from 0=no pain to 10=unbearable pain. The total morphine consumption in PCIA and the time of the bolus will be recorded. If the participants do not feel pain relief after injection of morphine from the PCIA, they will receive rescue anaesthetic as required by the assessment. The time and the dosage of analgesics in the first 48 hours will be recorded. A physiotherapist will evaluate the patients' postoperative ability; including the time taken for a patient to get out of bed, and perform physiotherapy exercises. Any postoperative complications, such as pneumonia, deep vein thrombosis, myocardial infarction, cerebrovascular accident and so on, will be recorded and treated. Additionally, any PENG block complications such as nerve damage, local anaesthetic

toxicity and vascular puncture will be recorded. A diagram of participant recruitment and secondary outcome measurement is shown in [table 1](#).

### Randomisation and blinding

At the beginning of this study, a randomisation sequence will be generated by SAS V.9.0 statistical software and assign the participants to either the control group (ultrasound-guided FN block group) or the intervention group (ultrasound-guided PENG block group) at a 1:1 ratio. An independent statistician will conceal the sequence (including allocated group, random numbers and intervention information) from the researcher, who will assess the subjects, in identical opaque and sealed envelopes.

The effect of the block will be evaluated and recorded by an investigator who is blinded in the block performance analysis.

### Sample size estimation

Based on the results of preliminary experiments, the QoR-15 scores (mean difference  $\pm$ SD) of elderly patients for 24 hours were 88.25 $\pm$ 8.32 in the FN block group and 98.97 $\pm$ 10.37 in the PENG block group. Myles *et al*<sup>25</sup> found that the minimal clinically important difference for the QoR-15 is 8.0. Therefore, to detect the effect size (power=0.8) with the type 1 error of 5% ( $\alpha$ =0.05), a dropout rate of 10% and a non-inferiority or superiority margin of 8, a sample size of 92 participants are required. As a result, 46 participants per group will be recruited for this study.

### Reporting of adverse events

Participants will be seen daily for the duration of the study. All adverse events and other unintended effects of the trial will be recorded. If any serious complications occur, researchers will be informed immediately, medical practitioners will then take proper measures to ensure the safety of patients. After the treatment, the allocated group of the patient will be revealed, and the evaluation about the correlation between adverse events and intervention will be discussed comprehensively. All details of any serious adverse events will be recorded and reported to the ethics committee.

### Patient and public involvement

Patients or the public were not involved in the design, conduct, reporting or dissemination plans of this research.

### Ethics and dissemination

This trial received ethical approval from the Institutional Review Board of the Ethics Committee of The First Affiliated Hospital of Guangzhou University of Chinese Medicine on 15 December 2020 (reference K2020-110). This study has been registered at the Chinese Clinical Trial Registry. The trial will be conducted in accordance with the Declaration of Helsinki 1996, principles of good clinical practice and the Department of Health Research Governance Framework for Health and Social Care. The researchers will send regular reports about the progress and any changes to this trial to the Institutional Review Board of the Ethics Committee of The First Affiliated Hospital of Guangzhou University of Chinese

**Table 1** Trial process chart

Items	The time before surgery	30 min after block	Postoperative 6 hours	Postoperative 12 hours	Postoperative 18 hours	Postoperative 24 hours	Postoperative 48 hours
	Inclusion criteria	x					
Exclusion criteria	x						
Informed consent	x						
Randomisation and allocation	x						
The rest pain score	x	x	x	x	x	x	x
The dynamic pain score	x	x	x	x	x	x	x
The strength of quadriceps	x	x	x	x	x	x	x
The consumption morphine	x	x	x	x	x	x	x
The rescue analgesic use	x	x	x	x	x	x	x
The time of the bolus	x	x	x	x	x	x	x
The first out-of-bed time	x	x	x	x	x	x	x
The postoperative complications			x	x	x	x	x
The PENG block complications		x	x	x	x	x	x
Others	x	x	x	x	x	x	x

PENG, pericapsular nerve group.

Medicine. The results of this study will be published in peer-reviewed international journals.

### Data management and monitoring

Demographic data and mental assessment data, QoR-15 data and information on pain scores, mobilisation assessment data and information about complications will be collected and input into an electronic database. An independent researcher will guarantee the data quality during the process. All data of outcomes will be input into another independent database and will be double checked to promote data quality. Any individual privacy information will be deleted to protect confidentiality. After data storage, only researchers will have direct access to the final trial data set. The progress and safety of this study will be monitored monthly by the data monitoring committee (DMC), which is composed of two independent experts outside the study. The clinical experts will be able to access the unblinded data. The DMC will be able to give suggestions regarding safety and will also have authority to terminate the trial. The final trial data set will be managed by The First Affiliated Hospital of Guangzhou University of Chinese Medicine. Accessing the data set will require the written permission of the corresponding author.

### Statistical analysis

All allocated subjects with available data will be analysed. According to the variable type and distribution, data will be presented as mean and SD, frequency and proportion or median and IQR (25th-75th percentile). Based on the  $\chi^2$  test or Fisher's exact test, categorical variables will be evaluated. The parametric t test, the Wilcoxon rank-sum test or the Kruskal-Wallis test will be used to analyse differences between the two groups in continuous variables. Non-normal distributions will be assessed with the Mann-Whitney U test. To manage missing data, mean completer and regression will be used. A p value of <0.05 will be considered statistically significant, and results will be presented with 95% CIs. Analysis of data will be performed with SPSS software V.21.0 (developed by IBM, Armonk, New York, USA).

### DISCUSSION

Hip fracture is often associated with serious pain. Lack of sufficient pain treatment can lead to not only the deceleration of recovery after surgery but also high risk of cardiovascular adverse events and long-term chronic pain.<sup>4</sup> Because of this, adequate pain treatment is needed in the perioperative period for more effective recovery.

Opioid use could be appropriate for the requirement of pain relief after surgery, so it has been the mainstay of potent analgesia for hip fractures worldwide in the past 20 years.<sup>26-28</sup> Simoni *et al*<sup>29</sup> found that 26.8% of patients redeemed one or more opioid prescriptions before surgery, and 61.8% received opioid therapy post-operatively. However, opioid-related adverse events are more common among the elderly, occurring in 80% of patients. These adverse events, including cognitive



impairment and increased fall risk (and in some cases, mortality), seriously delay rehabilitation after surgery. In addition, opioids offer pain relief at rest but are ineffective at addressing pain on movement.

Therefore, to reduce related adverse events and improve patients' experience, neuraxial techniques have been recommended. Consistent evidence has suggested that regional analgesia techniques can reduce pain by providing reasonable, rapid-onset and site-specific analgesia, which is more effective than traditional systemic analgesia.<sup>30</sup> In addition, there is evidence that peripheral nerve block may decrease the incidence of delirium, shorten hospital stays and reduce morbidity and mortality.<sup>30</sup> Following the development of ultrasound guidance, the success rate of peripheral nerve block has improved.<sup>31</sup> Thus, peripheral nerve block may have an excellent effect on fast-track recovery.

Nowadays, the FN block, FIC block and 3-in-1 FN block are popular peripheral nerve block techniques. Unfortunately, none of these nerve block techniques is ideal for hip fracture at present. According to multiple anatomical studies, the articular branches of FN, ON and AON innervate the anterior hip joint, which plays an important role in the innervation of the hip capsule.<sup>32–34</sup> This suggests that they should be the main target of regional analgesia. The three main nerves can be anaesthetised by 3-in-1 FN block and FIC block. However, the success rate of the ON block with 3-in-1 FN block falls between 77% and 80%, while the rate with FIC block is 88%.<sup>35</sup> So, both FIC block and the 3-in-1 FN block may result in failure to anaesthetise ON, and the FN block also cannot anaesthetise ON.<sup>35–37</sup> As a result, the effectiveness of these three blocks is moderate. In addition, these three nerve block techniques may produce quadriceps weakness, which could slow mobilisation and increase the incidence of falls.<sup>38</sup> Therefore, a new regional analgesia, one that can provide complete analgesia without significant motor dysfunction, should be put forward.

The PENG block, developed by Girón-Arango *et al.*<sup>12</sup> is a novel peripheral nerve block for patients with hip fracture. When Girón-Arango *et al.*<sup>12</sup> performed the PENG block in five patients, they found that the Numeric Rating Scale (NRS) for rest pain in four cases decreased from 4 points or above to 0 points, the reduction of NRS for dynamic pain in all five cases was more than 4 points, and the median reduction of pain was 7 points. Over 100 PENG blocks have been performed by Yu *et al.*<sup>39</sup> for hip fracture and surgery, and these blocks were also found to be highly effective. Ince *et al.*<sup>40</sup> combined PENG and lumbar erector spinae plane block to provide postoperative pain treatment in a 4-year-old child undergoing surgery for congenital hip dysplasia, and the FLACC (Face, Legs, Activity, Cry and Consolability) score in postoperative 24 hours was less than 1 point without any need for additional analgesics. Recently, some studies of PENG block have been published and suggested PENG block could provide effect analgesia with better preservation of motor function comparing with FN block or FIC block.<sup>16 41</sup>

These studies provide promising evidence about the effectiveness of PENG block for hip surgery. Perhaps most impressive is that this approach provides significant dynamic pain control with a motor-sparing effect, which makes the early mobilisation possible. PENG block seems to meet the conditions for an ideal peripheral nerve block for geriatric patients with hip fracture. Thus, this trial is set to test whether PENG block is effective to enhance recovery in elderly patients with hip fracture.

To test the quality of recovery, a variety of measurement tools could be chosen. Traditionally, many clinical observational indices are used to evaluate the effectiveness and safety of anaesthesia in postoperative recovery, but most are focused on the physiological end points such as the incidence of complications, the length of hospital stays, the mortality and so on. Although these indexes are objective and measure important data, evaluations from the patients' points of view are more humanised and are also important to be assessed. So, a patient-rated QoR-15 is suitable. It is a multidimensional measurement of quality of recovery demonstrated by high-quality evidence and includes five dimensions: pain, physical comfort, physical independence, psychological support and emotional state. Stark *et al.*<sup>22</sup> suggested that there was no relation between the QoR-15 and patient age, which indicates that the QoR-15 could be used in elderly patients. In addition, according to the positive impact duration of the regional anaesthesia, the time frame of the measurement instrument should be the early postoperative time.<sup>7</sup> As the result, some common assessment, which resulted at postoperative day 3 or later, may be not ideally suited. For these reasons, the QoR-15 at postoperative 24 hours was chosen as the primary outcome in this study.

This is a study using a randomised, parallel controlled, double-blind trial to compare QoR-15 between ultrasound-guided FN block and ultrasound-guided PENG block. It also explores the effectiveness and safety of PENG block in elderly patients after hip fracture surgery. The findings of this study may provide a new peripheral nerve analgesia for hip fracture, which could relieve pain without motor dysfunction to accelerate recovery. This will offer clinical evidence for the optimal analgesia method in Enhanced Recovery After Surgery pathways for elderly patients with hip fracture.

**Contributors** WL, JW and QL conceived of the study, designed the study protocol and drafted the manuscript. WL and QL wrote the manuscript. WM was in charge of coordination and direct implementation. JL and HW helped to develop the study measures and analyses. WL, JL, HW, and YL performed the trial. YO and JW input the data and guaranteed the data quality. HW and YL provided statistical knowledge for the study's initiation. All authors contributed to and approved the final manuscript.

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**Competing interests** None declared.

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**Patient consent for publication** Consent obtained directly from patient(s).

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