

Protocol

Erector spinae block for total hip arthroplasty

A prospective randomised double-blind placebo controlled trial to assess the efficacy of Erector Spinae Blocks for total hip arthroplasty

“B-Hip Study”

Investigators

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This protocol was developed using the guidelines provided in The Australian Clinical Trial Handbook (Therapeutic Goods Administration, 2006) and CONSORT guidelines (JAMA, December 26, 2012—Vol 308, No. 24)

1. Background and Summary of the Literature

A recent audit of quality of recovery following hip replacement at Hollywood Hospital indicated that a proportion of patients experience significant pain in the 1st 24h following surgery. The aim of this study is to reduce the reported incidence of severe pain following hip replacement particularly in the first 24h. Current approaches to pain management for hip arthroplasty include a 'spinal anaesthetic', supplemented by direct injection of local anaesthetic into the joint during surgery. This is combined with oral multimodal analgesia with paracetamol, anti-inflammatories, pregabalin and narcotic analgesia. Despite this multimodal approach to pain management, some patients still report severe pain. Additional techniques to improve pain management include nerve blocks such as femoral nerve block or lumbar plexus block. Both can be effective in reducing pain however may also cause some weakness of the muscles around the joint. This is a disadvantage as mobilisation may be delayed and there is a higher risk of falls. As a result these nerve blocks are not used routinely. In addition lumbar plexus blocks are technically challenging and not consistently effective. Furthermore there is a small risk of nerve injury if the needle is placed directly into a nerve. A newer form of nerve block termed an erector spinae block has been described for thoracic and abdominal surgery with isolated case reports for lower limb arthroplasty¹⁻³. The rationale for trialing this block is that it is technically easier and likely to be safer than a lumbar plexus block and may preserve muscle strength. A pilot audit of this nerve block technique in 33 patients at Hollywood found it to be safe and effective in reducing pain without any compromise to patient mobility. The injection is given under a muscle (the erector spinae muscle) close to a bony prominence called the transverse process of the 2nd or 3rd lumbar vertebrae. The injection is performed under direct real time ultrasound imaging and the injection site is 1-2cm away from the nerve roots and therefore unlikely to cause nerve injury.

2. Trial objective and purpose

Primary Outcome

1. Pain score with movement at 6 hours following surgery
 - a. Numeric rating scale 0 (no pain) to 10 (most severe pain)

Secondary Outcomes

1. Pain scores at rest and with movement at 6, and 24 hours postoperatively
2. Quality of recovery score at 24 hours postoperatively
 - a. QoR-15 questionnaire
3. Mobilisation data
 - a. Ability to stand on the day of surgery
 - b. Ability to walk 5m on Day 1 AM
 - c. Ability to walk 20m on Day 1 PM
 - d. Ability to walk 40m on Day 2
4. Length of stay

3. Summary of benefits and risks

Benefits

Patients in the treatment group may receive additional analgesia and report lower pain scores following hip replacement.

Risks

Risk of nerve injury is low with this technique. Anatomically the site of the injection is posterior to nerve roots and the risk of intraneural injection is low due to real time ultrasound imaging. Muscle weakness is possible and needs to be assessed prior to mobilisation as is routine for this kind of surgery. Local anaesthetic toxicity, bleeding or infection risks are all very low.

Risk	Cause	Risk Mitigation
Nerve injury	Direct injection of nerve by needle tip.	Use of high fidelity ultrasound and highly experienced operators. Estimated risk <1:5000
Local anaesthetic toxicity	Accumulation of local anaesthetic in circulation. Higher risk if intravascular placement and bolus administered.	30mls of 0.2% ropivacaine maximum dose via nerve block which is within recommended safety guidelines
Muscle weakness and falls	Quadriceps weakness	Daily quadriceps assessment prior to mobilisation, which is embedded as standard practice for this type of surgery. Education to patients.
Bleeding or infection at the injection site	Perforation of blood vessels or contamination by local bacteria	No significant vasculature in the block site. Infection is considered rare. When catheters are inserted into nerve block sites and left in place for several days the quoted infection rates are ~1:1500

4. Trial Design

Prospective placebo controlled double blind randomised trial

Inclusion Criteria

1. Adults, aged > 18 years old, not pregnant

2. Elective unilateral total hip arthroplasty
3. Mentally competent to provide informed own written consent in English

Exclusion:

1. Eligible patients who are unable or unwilling to consent
2. Failure of spinal anaesthetic technique
3. Change in planned surgical technique leading to more complex surgery for example unanticipated femoral fracture requiring additional procedures
4. Significant preoperative neuromuscular condition limiting mobility
5. Chronic opioid use > 40mg/d oral morphine equivalent
6. Revision surgery, bilateral surgery
7. Allergy or sensitivity to local anaesthetics

Withdrawal:

1. Postoperative confusion resulting in inability to complete the questionnaires
2. Patient requests voluntary withdrawal.

Randomisation:

Patients will be assigned to receive either local anaesthetic or placebo (1:1 allocation, parallel trial design), based on a computer-generated randomisation list created by an independent researcher. All patients and anaesthetists performing the block will be blinded. This will be facilitated by anaesthesia technicians opening a randomisation envelope and delivering local anaesthetic or placebo as indicated as a clear fluid onto the anaesthetic block trolley for subsequent injection by the anaesthetist. The anaesthetist will not be aware which fluid has been dispensed. Assessors collecting the data postoperatively will not be aware which group the patient has been assigned to.

Description of erector spinae block

The patient will be positioned in a lateral position in the anaesthetic room and routine monitoring applied. The anaesthetist will provide intravenous sedation to facilitate patient comfort during the spinal injection as is usual for this procedure. The skin will be sterilised with chlorhexidine and the needle entry site anaesthetised with 1% lignocaine. Ultrasound guidance will be used to identify the transverse process of the 2nd lumbar vertebra and 30mls of 0.2% ropivacaine (or placebo) will be slowly injected over the transverse process below the plane of the erector spinae muscle. This should take 2-3 minutes to complete. The patient will then receive a continuous infusion of propofol for deep sedation or general anaesthesia according to the preference of the anaesthetist and patient and surgery will proceed.

5. Ethical Considerations

Informed consent

The risks and benefits of participation in the study will be explained to each subject by the investigator in order to obtain informed consent. A patient information sheet will be provided to the patients at the time of the booking of surgery. Patients will be given time to read and understand the information sheet. The consent form, as approved by the Ethics committee will contain details of the trial in language readily understood by the subject. Each subject's original consent form, signed and dated by the subject will be retained by the investigator and a copy will be given to the subject.

Should a patient not provide consent they will be assured that their treatment will not be affected in any adverse way and they will not be disadvantaged. All patients will be entitled to withdraw consent from participation at any time throughout the trial.

Protocol amendments

All protocol amendments will be submitted in writing to the Ethics Committee

Safety and Adverse Event Reporting

Adverse events will be recorded on an Adverse Event Record sheet and will be discussed with the study group steering committee. Any safety concerns from the team will be reported to the Ethics Committee as soon as possible.

Quality control and quality assurance

This study will be conducted in compliance with the conditions stipulated by the Ethics committee, informed consent regulations and Good Clinical Practice guidelines. All local regulatory requirements will be adhered to and in particular those which afford greater protection to the safety of the trial participants.

All amendments to the trial will be submitted to the Ethics committee for approval. Any information that may influence the committees' decision to continue the trial will be forwarded to the committees without delay.

Protocol compliance statement

The trial will be conducted in compliance with the protocol, good clinical practice (GCP) and the applicable regulatory requirement(s).

6. Data collection

Personal information of age, sex, height, weight, mobilisation data and operation details will be obtained from patient records. Patient diaries will be collected from patients and data entered into a secure password protected database. Access to the data will be restricted to investigators only.

Record of participation, diary and copy of health questionnaires specific to the study will be electronically stored for approximately 5 years, after which time they will be destroyed by file deletion or shredding.

7. Statistical Analysis

Pain scores will be presented as a numeric rating scale and the median and interquartile range reported. The study will be powered to detect a 2 point difference in pain scores at 6 hours, which requires 29 in each group. Allowing for attrition we will target 32 per group for a total of 64 patients.

8. Financing and Insurance

Patients will not be subject to any additional costs.

9. Publication policy

It is intended that the study results be published in a peer-reviewed journal without personal details of individual patients, with acknowledgment of any study personnel who have contributed significantly with additional reference to Hollywood Private Hospital.

10. References

1. Forero M, Adhikary SD, Lopez H, Tsui C, Chin KJ. The erector spinae plane block: a novel analgesic technique in thoracic neuropathic pain. *Reg Anesth Pain Med* 2016;41:621-627
2. Tulgar S, Senturk O. Ultrasound guided erector spinae plane block at L4 transverse process level provides effective postoperative analgesia for total hip arthroplasty. *J Clin Anesth* 2017;44:68
3. Tulgar S, Selvi O, Senturk O, Ermis MN, Cubuk R, Ozer Z. Clinical experiences of ultrasound-guided lumbar erector spinae plane block for hip joint and proximal femur surgeries. *J Clin Anaesth* 2018;47:22-23