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Comparison of Stimulating versus Non-stimulating catheter technique for Continuous Interscalene Brachial Plexus block by Posterior approach for shoulder surgery

Submission date
28/09/2007

Recruitment status
No longer recruiting

Registration date
28/09/2007

Overall study status
Completed

Last Edited
14/08/2015

Condition category
Surgery

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N0084186835

Study information

Scientific Title

Comparison of Stimulating versus Non-stimulating catheter technique for Continuous Interscalene Brachial Plexus block by Posterior approach for shoulder surgery

Study objectives
Limb surgeries can cause considerable pain after the operation. One of the most effective methods of relieving this pain is to use a procedure called Nerve Plexus Block, which numbs the nerves carrying pain sensation from the operation site. To provide pain relief continuously for next few days, catheters (small plastic tube) are inserted close to the nerves whilst doing the block and left in place, so that local anaesthetic can be delivered through it continuously. In order to identify nerves we use nerve stimulators. When needle is accurately located, we put in the catheter through the needle. There are two types of catheters:
1. Continuous stimulating catheter where it has the advantage of having nerve stimulating facilities which helps to make sure catheter is still in the right place
2. Continuous non-stimulating catheter which is exactly the same as above without nerve stimulating facility.

The purpose of this study is to compare the two types of catheters when used for nerve plexus block for shoulder surgeries with respect to ease of catheter placement, onset of block and efficacy of pain relief.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Surgery: Shoulder

Interventions
Introduction:
Continuous Interscalene nerve plexus block is a pain relief technique offered to all patients coming for shoulder surgeries as a routine. It involves identifying and numbing the nerves conveying pain sensation from shoulder. This is provided continuously by placing a catheter.

The purpose of this study is to:
Compare Stimulating and Non-Stimulating catheter technique for continuous ISB (interscalene nerve block) posterior approach for shoulder surgeries in terms of their catheter placement time, efficacy, onset of block, post op pain score, primary (during the operation) and secondary (after the operation) pain relief failure rate, patient satisfaction and catheter compliance.

Those enrolled in the study would be patients coming for elective shoulder surgeries in the orthopaedic list at Castle Hill hospital. Patients would be admitted the day before surgery, pre-assessed, given information regarding this study and screened whether they full fill the criteria. If they are happy to participate in the study, they would be consented.

Methodology:
This study would be prospective, randomised and single blinded. Randomisation would be computer generated. Once patients satisfy criteria informed consent would be obtained during pre-assessment, the day before the operation. Randomisation would be to one of the two groups:
1. Group A = Non-stimulating catheter for continuous ISB
2. Group B = Stimulating Catheter for Continuous ISB
The patient would come with a sealed envelope to the anaesthetic room and the procedure would be depending on the technique mentioned in the envelope.

Outcome measures:
Catheter placement time (from the time needle to the skin to application of sticky plaster), and ease of placement would be noted.
Sensory and Motor block would be assessed at 5, 10, 15, 20, 30 minutes and time zero would be designated at the end of local anaesthetic injection. Before surgery, a separate investigator would assess the block.
Post-operative:
Assessment of pain scores at rest will be done using Verbal Rating Score graded from 0 (no pain) to 4 (worst imaginable pain) for as long as catheter is required post op (would be done by different person blinded to the technique).
Patient satisfaction score with respect to catheter placement would be graded as excellent, good, poor or unsatisfactory.

Care for patients in both groups will be identical.

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome(s)
1. Catheter placement time (time from insertion of needle to applying sticky plaster)
2. Onset of sensory and motor blockade (time from LA injection to Block of all dermatomes)
3. Efficacy of analgesia (intra op analgesic needed, Post op VAS scores and post op LA required and Opiates needed)

Key secondary outcome(s))
Not provided at time of registration

Completion date
31/07/2008

Eligibility

Key inclusion criteria

1. Patients 18 years & over for elective shoulder surgery
2. ASA 1 and 2 patients.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Not Specified

Key exclusion criteria
1. ASA 3 & 4 patients
2. Patients on anticoagulants
3. Allergic to local anaesthetic
5. Known neurological damage to the concerned limb

Date of first enrolment
28/09/2006

Date of final enrolment
31/07/2008

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
42 Blackburn Avenue
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Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Funder(s)

Funder type
Government

Funder Name
The North and South Bank Research and Development Consortium (UK)

Funder Name
Hull & East Yorkshire Hospitals NHS Trust (Endowment Fund) (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration