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Effective lidocaine volume for a double-injection costoclavicular brachial plexus block

Submission date
06/11/2025

Recruitment status
Recruiting

Registration date
11/11/2025

Overall study status
Ongoing

Last Edited
20/11/2025

Condition category
Surgery

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

Plain English summary of protocol

Background and study aims:
The costoclavicular block is a regional anesthesia technique for the upper extremity. The block has proven to be effective and safe to offer anesthesia and analgesia for upper extremity surgery. Recently it was demonstrated that depositing the local anesthetic in two locations is more efficient than in just one for this technique. However, the volume of local anesthetic needed when using two injections is unknown and might be different and perhaps lower than with single injections. The aim of this study is to determine the ideal volume to use in this double injection technique. This is important because knowing the effective volume it is possible to prevent unnecessary high and possibly toxic doses of local anesthetics.

Who can participate?
Patients between 18 and 70 years old undergoing upper limb surgery (elbow, forearm, wrist or hand) at the Montreal General Hospital.

What does the study involve?
Patients agreeing to participate will undergo surgery under a costoclavicular block. The block will be performed by specialists in regional anesthesia before surgery, in a dedicated area for this procedure with monitoring and access to sedation if required.
Lidocaine volume used for the block will be based on the response of the previous patient as follows: if the previous patient did not have a successful block, the patient will receive the next higher dose (2.5 ml higher). If the previous patient had a successful block, the next dose will be decided by chance, with a probability to receive a 2.5 ml lower dose of 11%, or to receive the same dose, with a probability 89%. A maximal volume is predetermined to avoid toxicity. If the previous patient did not respond and had been given the maximal volume the next patient will also get the maximal volume.
Through an statistical analysis of successful and failed blocks with differences volumes received, the dose most possibly effective for 90% of cases will be defined.

What are the possible benefits and risks of participating?
The study does not represent any special benefit for the participants. By determining the minimum effective volume of lidocaine, the risks of local anesthetic related systemic toxicity are potentially reduced.

Participation in this protocol will not put patients at higher risk for complications since we use a similar technique for US-guided double-injection costoclavicular block independently of study enrollment. Clinical success of the block will not be affected by study participation as subjects failing to achieve a complete block after 30 minutes will receive local anesthesia supplementation through the catheter installed just after administrating the studied volume. Furthermore, side effects associated with costoclavicular blocks are rare. Our experience reveals a very low incidence of vascular puncture.

Where is the study run from?
The study will be conducted at the Montreal General Hospital, Montreal, Quebec, Canada.

When is the study starting and how long is it expected to run for?
The study will start after it is made public. Expected start date: 01/12/2025. Expected recruitment duration: 6 months.

Who is funding the study?
This study is funded by the Department of Anesthesia of the Montreal General Hospital, McGill University Health Centre, Montreal, Canada.

Who is the main contact?
Dr Julián Aliste, julian.aliste@mcgill.ca

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Julián Aliste

ORCID ID
https://orcid.org/0000-0001-6355-1270

Contact details
D10 1650 Cedar Avenue
Montreal
Canada
H3G 1A4
+1 (0)514 934 1934 ext 43261
julian.aliste@mcgill.ca

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number

2026-11651

Study information

Scientific Title
Minimum effective volume of lidocaine for double-injection ultrasound-guided costoclavicular block

Study objectives
The efficacy of a double-injection costoclavicular block depends on the volume injected. This study seeks to determine the minimum effective volume in 90% of patients (MEV90) for lidocaine to block the brachial plexus.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 24/09/2025, McGill University Health Centre Research Ethics Board (5100, boul. de Maisonneuve Ouest, 5th floor, Office 596, Montreal, H4A 3T2, Canada; +1 (0)514 934 1934 ext 36077; reb@muhc.mcgill.ca), ref: 2026-11651

Study design
Sequential allocation via biased coin and up-and-down methodology

Primary study design
Interventional

Study type(s)
Efficacy

Health condition(s) or problem(s) studied
Brachial plexus nerve block for upper extremity surgery

Interventions
Patients undergoing upper extremity surgery (elbow and below) under a double-injection costoclavicular brachial plexus block will be assigned to a predetermined volume of adrenalized 1.5% lidocaine.

Dose assignment will be done using an up-and-down sequential method, where the dose of each subsequent patient depends on the response of the previous patient, called the Biased Coin Design (4). The first subject recruited will receive a total of 30 ml of lidocaine 1.5 % with epinephrine 1: 200 000, divided into two equal aliquots of 15 ml for each of the two injection sites. Injection will be carried out by slow increments (5 ml) with negative aspiration between each increment.

The assignment of each subsequent dose will be based on the response of the previous patient as follows: if the previous patient did not have a successful block, the patient will receive the next higher dose, which is the previous dose incremented by 2.5 ml (i.e., an increment of 1.25 ml for each of the two injection sites). If the previous patient had a successful block, the patient will be randomized to either receive the next lower dose, which is the previous dose decremented by

2.5 ml (i.e., a decrement of 1.25 ml for each of the two injection sites), with a probability b = 0.11, or to receive the same previous dose, with a probability 1 – b = 0.89. These are the probabilities required for assigning doses under the BCD for estimating ED90 (5). A maximal dose of 40 ml will not be exceeded to avoid LA toxicity. If the previous patient did not respond and had been given the maximal dose, the patient will also get the maximal dose.

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Lidocaine

Primary outcome(s)
Success rate (binary outcome): dose-response data will be used to estimate the minimum effective volume of LA required to successfully anesthetize the brachial plexus in 90% of patients.
Success definition: Using a previously reported 16 point sensorimotor scale for musculocutaneus, radial, median and ulnar nerves. A block will be considered successful if, at 30 minutes (after injection), a composite score of at least 14 points (out of a maximum of 16) is obtained. This score has been proven to provide a reliable estimate of surgical anesthesia.
Sensory blockade will be graded with a 3-point scale using a cold test to each nerve sensory regions: 0 = no block, 1 = analgesia (patient can feel touch, not cold), 2 = anesthesia (patient cannot fee touch) (3). The cold test will be applied with light touch to avoid confusion with deep pressure sensation.
Motor blockade will also be graded on a 3-point scale by elbow flexion (musculocutaneous), thumb abduction (radial), thumb opposition (median) and thumb adduction (ulnar).: 0 = no block, 1 = paresis, 2 = paralysis (3).

Key secondary outcome(s))
1. Operator's level of experience (binary): expert vs trainee (expert defined as an experienced operator of a minimum of 60 costoclavicular blocks)
2. Number of needle passes (count): after needle insertion, any needle adjustment requiring 10 mm retraction will be considered an extra pass
3. Performance time (seconds): time necessary to guide the needle to the desired locations
4. Patient discomfort measured using a Visual Analog Scale (VAS) during the block: 0 = minimum discomfort and 10 = maximum discomfort
5. Demographic data:
5.1. Sex (binary): male/female
5.2. Age (years)
5.3. Weight (kilograms)
5.4. Height (centimeters)
5.5. Type of surgery (count): elbow/forearm/wrist/hand
6. Side effects:
6.1. Vascular puncture (binary): yes/no (ultrasound evidence of vascular puncture or blood reflux trough block needle)
6.2. Hematoma at the site of puncture (binary): yes/no (ultrasonographic or clinical evidence of hematoma)
6.3. Toxic effects of LA (binary): yes/no (presence of clinical signs of systemic toxicity to local

anesthetics: tinnitus, perioral paresthesia, confusion, seizures, ECG alterations)
6.4. Hoarseness (binary): yes/no
6.5. Phrenic nerve block (count): normal/paresis/paralysis (by ultrasound-assessed excursion change from baseline before block, excursion decrease >25% = paresis, excursion decrease >75% = paralysis)
6.6. Horner's syndrome (binary): yes/no (clinical signs)

Completion date
01/12/2026

Eligibility

Key inclusion criteria
1. Surgery of the distal upper extremity under brachial plexus block
2. Age between 18 and 70 years
3. American Society of Anesthesiologists classification 1-3
4. Body mass index between 20 and 30 kg/m²

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
70 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Adults who are unable to give their own consent
2. Pre-existing neuropathy (assessed by history and physical examination)
3. Coagulopathy (assessed by history and physical examination and, if deemed clinically necessary, by blood work up i.e. platelets ≤100, International Normalized Ratio≥ 1.4 or partial prothrombin time ≥ 50)
4. Renal failure (assessed by history and physical examination and, if deemed clinically necessary, by blood workup up i.e. creatinine ≥100)
5. Hepatic failure (assessed by history and physical examination and, if deemed clinically necessary, by blood workup up i.e. transaminases ≥100)
6. Allergy to local anesthetics

7. Pregnancy
8. Prior surgery in the infraclavicular region
9. Chronic pain syndromes requiring opioid intake at home

Date of first enrolment
17/11/2025

Date of final enrolment
30/06/2026

Locations

Countries of recruitment
Canada

Study participating centre
Montreal General Hospital
1650 Cedar Avenue
Montreal
Canada
H3G 1A4

Sponsor information

Organisation
McGill University Health Centre

ROR
https://ror.org/04cpxjv19

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Montreal General Hospital

Funder Name
McGill University Health Centre

Results and Publications

Individual participant data (IPD) sharing plan

The deidentified datasets generated during and/or analyzed during the current study will be available upon reasonable request from Julián Aliste (julian.aliste@mcgill.ca)

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes