

CLINICAL TRIALS REGISTRY - INDIA

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CTRI Website URL - <http://ctri.nic.in>

## Clinical Trial Details (PDF Generation Date :- Tue, 21 Mar 2023 08:29:02 GMT)

<b>CTRI Number</b>	CTRI/2020/11/029359 [Registered on: 25/11/2020] - <b>Trial Registered Prospectively</b>	
<b>Last Modified On</b>	08/06/2022	
<b>Post Graduate Thesis</b>	No	
<b>Type of Trial</b>	Interventional	
<b>Type of Study</b>	Surgical/Anesthesia	
<b>Study Design</b>	Randomized, Parallel Group Trial	
<b>Public Title of Study</b>	Effect of different local anaesthetic drugs and combinations on onset of block action.	
<b>Scientific Title of Study</b>	To determine the latency of three local anaesthetic solutions during ultrasound guided supraclavicular brachial plexus block for forearm bone surgeries – A double blind randomized control trial.	
<b>Secondary IDs if Any</b>	<b>Secondary ID</b>	<b>Identifier</b>
	NIL	NIL
<b>Details of Principal Investigator or overall Trial Coordinator (multi-center study)</b>	<b>Details of Principal Investigator</b>	
	<b>Name</b>	Sripriya R
	<b>Designation</b>	Professor
	<b>Affiliation</b>	MGMCRI, Puducherry
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	> Mahatma Gandhi Mediacollege and research Institute, Pilliyarkuppam, Pondicherry 607402			
<b>Primary Sponsor</b>	<b>Primary Sponsor Details</b>			
	<b>Name</b>	nil		
	<b>Address</b>	NA		
	<b>Type of Sponsor</b>	Other [NA]		
<b>Details of Secondary Sponsor</b>	<b>Name</b>	<b>Address</b>		
	NIL	NIL		
<b>Countries of Recruitment</b>	<b>List of Countries</b>			
	India			
<b>Sites of Study</b>	<b>Name of Principal Investigator</b>	<b>Name of Site</b>	<b>Site Address</b>	<b>Phone/Fax/Email</b>
	sripriya R	MGMCRI	Department of anaesthesiology, 2nd floor, OT complex Pondicherry PONDICHERRY	9365815939  docsripriya@gmail.com
<b>Details of Ethics Committee</b>	<b>Name of Committee</b>	<b>Approval Status</b>	<b>Date of Approval</b>	<b>Is Independent Ethics Committee?</b>
	Institutional human ethics committee	Approved	25/09/2020	No
<b>Regulatory Clearance Status from DCGI</b>	<b>Status</b>		<b>Date</b>	
	Not Applicable		No Date Specified	
<b>Health Condition / Problems Studied</b>	<b>Health Type</b>		<b>Condition</b>	
	Patients		Unspecified fracture of forearm	
<b>Intervention / Comparator Agent</b>	<b>Type</b>	<b>Name</b>	<b>Details</b>	
	Intervention	three local anaesthetics for supraclavicular brachial plexus block	Group LB: Patients receiving 10ml 0.5% bupivacaine + 10 ml 2% lignocaine with adrenaline pre-mixture.	
	Comparator Agent	local anesthetic drugs	Group L: Patients receiving 20 ml 2% lignocaine with adrenaline premixture. Group B: Patients receiving 20 ml 0.5% bupivacaine.	
<b>Inclusion Criteria</b>	<b>Inclusion Criteria</b>			
	<b>Age From</b>	18.00 Year(s)		
	<b>Age To</b>	60.00 Year(s)		
	<b>Gender</b>	Both		
	<b>Details</b>	ASA grade I and grade II undergoing elective or emergency procedure for upper limb bone surgeries at or below the elbow.		
<b>Exclusion Criteria</b>	<b>Exclusion Criteria</b>			
	<b>Details</b>	1. Patient refusal for the block. Patients refusing the block will be administered general anaesthesia.		

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	<ol style="list-style-type: none"> <li>2. History of bleeding disorders</li> <li>3. Local infection at the site of block</li> <li>4. Pre-existing neurological deficit</li> <li>5. Cardio-Respiratory compromise.</li> <li>6. Known allergy to local anesthetic drug.</li> <li>7. Patients in whom the supraclavicular sono-anatomy is not clear.</li> </ol>				
<b>Method of Generating Random Sequence</b>	Permuted block randomization, variable				
<b>Method of Concealment</b>	Sequentially numbered, sealed, opaque envelopes				
<b>Blinding/Masking</b>	Participant, Investigator and Outcome Assessor Blinded				
<b>Primary Outcome</b>	<table border="1"> <thead> <tr> <th>Outcome</th> <th>Timepoints</th> </tr> </thead> <tbody> <tr> <td>to compare time to complete conduction block in the four terminal nerve areas</td> <td>10 , 20 , 30, 40 minutes</td> </tr> </tbody> </table>	Outcome	Timepoints	to compare time to complete conduction block in the four terminal nerve areas	10 , 20 , 30, 40 minutes
Outcome	Timepoints				
to compare time to complete conduction block in the four terminal nerve areas	10 , 20 , 30, 40 minutes				
<b>Secondary Outcome</b>	<table border="1"> <thead> <tr> <th>Outcome</th> <th>Timepoints</th> </tr> </thead> <tbody> <tr> <td>to compare the duration of analgesia in the three groups</td> <td>10, 20, 30 , 40 minutes</td> </tr> </tbody> </table>	Outcome	Timepoints	to compare the duration of analgesia in the three groups	10, 20, 30 , 40 minutes
Outcome	Timepoints				
to compare the duration of analgesia in the three groups	10, 20, 30 , 40 minutes				
<b>Target Sample Size</b>	<b>Total Sample Size=63</b> <b>Sample Size from India=63</b> <b>Final Enrollment numbers achieved (Total)=0</b> <b>Final Enrollment numbers achieved (India)=0</b>				
<b>Phase of Trial</b>	Phase 1				
<b>Date of First Enrollment (India)</b>	01/12/2020				
<b>Date of First Enrollment (Global)</b>	No Date Specified				
<b>Estimated Duration of Trial</b>	<b>Years=0</b> <b>Months=6</b> <b>Days=0</b>				
<b>Recruitment Status of Trial (Global)</b>	Not Applicable				
<b>Recruitment Status of Trial (India)</b>	Completed				
<b>Publication Details</b>	There are no publications yet. nil.				
<b>Brief Summary</b>	<p>In this study one group of patients will be receiving block with a drug that is fast acting. One group of patients will be receiving block with a drug that takes some more time to begin acting. Yet an other group will receive a combination of the two drugs. You will have an equal chance of being included in any of the groups. After the injection is done, we will test you at 10 minute intervals to get information on how much time it takes to produce complete loss of sensation and complete loss of motor power. After that, the surgery will begin. After the surgery is over, we will continue to follow up till you first perceive pain.</p>				

To determine the latency of three local anaesthetic solutions during ultrasound guided supraclavicular brachial plexus block for forearm bone surgeries – A double blind randomized control trial.

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DR. R. SRIPRIYA DNB (Anaes)  
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#### PRINCIPLE INVESTIGATOR

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#### COINVESTIGATORS

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## 1 INTRODUCTION

The onset of complete conduction blockade following supraclavicular brachial plexus block depends on two major factors namely the proximity of injected drug to the neural elements and the drug characteristics. Proximity to the neural elements depends on the guidance (landmark, nerve stimulator, ultrasound) used (1). Consistent success with ultrasound guided multipoint sub-fascial injection of SCBP has been previously demonstrated.

Among the drug characteristics, the type of local anaesthetic (rapid onset-short acting vs slow onset-long acting), volume and concentration of LA are the important drug characteristics influencing onset. Combination of local anesthetics is used frequently to compensate for the delayed onset of one agent ( bupivacaine) and the short duration of action of the other agent ( Lignocaine) (3,4). Miller has cautioned on the use of maximum doses of two LA in a mixture as the toxicity of such combinations are additive (5).

Clinical studies evaluating the efficacy of such combinations provided variable results due to the differences in guidance device, injection techniques, local anesthetic drug as well as the clinical end points used for defining success. Jeff Gadsden et al have observed that, for ultrasound guided interscalene block, a combination of mepivacaine 1.5% and bupivacaine 0.5% resulted in a block onset similar to either anaesthetic alone (6). However, in our clinical experience, we have observed that the onset of action of SCBPB is delayed with bupivacaine when compared to drug combinations.

Hence, we designed this study to determine the effect of lignocaine- bupivacaine combination with either drug given alone on block onset of complete conduction blockade and duration of analgesia during Ultrasound Guided Supraclavicular Brachial Plexus Block.

## 2 AIMS AND OBJECTIVES

1. **Aim** : To assess the onset of complete conduction blockade and Duration of Analgesia following SCBPB using three different LA solutions. 20 ml of equivolume mixture of 0.5% bupivacaine + 2% lignocaine (2.5 mcg/ml adrenaline), 20 ml 0.5 % bupivacaine and 20 ml of 2% lignocaine (5 mcg/ml adrenaline).

2. **Objectives:**



- a. To compare the time to complete sensory block in each of 4 major nerve distribution areas: Median, Radial, Ulnar, Musculocutaneous nerves on an qualitative scale of 0, 1, 2 in the three groups.
- b. To compare the time to complete Motor Block in each of 4 major nerve distribution areas: Medial, Radial, Ulnar, Musculocutaneous nerves on an qualitative scale of 0, 1, 2 in the three groups.
- c. To compare the Duration of Analgesia in the three groups.

### 3 REVIEW OF LITERATURE

**1)** Two different techniques of injecting local anaesthetic drugs under ultrasound guidance for supraclavicular Brachial Plexus Block was compared by *Sivashanmugam et al.* They performed a randomised comparative study in 32 patients undergoing upper extremity surgery. A 1:1 mixture of local anaesthetics (2% lignocaine with adrenaline and 0.5% bupivacaine) 25 ml was injected subfascially or extrafascially to the brachial plexus sheath. They assessed the Block Onset time and duration of post operative analgesia. Their study concluded that subfascial injection provided faster onset (7 +3) min than extrafascial (20 + 10) min and longer duration of analgesia subfascial (9.3 + 1.4) and extra fascial (6.1 + 1.4) hours.

**2)** That mixing of two types of local anaesthetics (faster onset with intermediate duration and slower onset with long duration) would reduce the peripheral nerve block onset by 20% or more than using long acting local anaesthetics was stated by *Laur JJ et al.* They performed a randomised triple blinded study in 3 study groups in 93 patients (GROUP 1- 1.5% mepivacaine with epinephrine, GROUP 2 - 1.5% mepivacaine with epinephrine and 0.5% bupivacaine, GROUP 3 - 0.5% bupivacaine alone for Infraclavicular block. Their study concluded that 1.5% mepivacaine with epinephrine and 0.5% bupivacaine produced faster onset 17(12-21) min than 0.5% bupivacaine alone 21(12-24) min in Landmark Guided Infraclavicular Block.

**3)** Whether addition of 2% Lignocaine to 0.5% bupivacaine provided a decreased block onset time and drug effect time when compared with 0.5% bupivacaine alone in landmark guided Lateral Sagittal infraclavicular block was investigated by *Ozgur OZMEN et al.* The study was carried out in 120 patients undergoing upper extremity surgery who were randomly divided into 3 groups each group containing 40 patients. Group B received 20ml of 0.5% bupivacaine, Group B+L received 10ml of 0.5% bupivacaine + 10ml of 2% lignocaine and Group L received 20ml of 2% lignocaine. Their study concluded that the block onset time is very long in Group B (9.7 + 1.86) min than other two groups [ Group B+L 4.0+1.31 min, Group L 4.4+1.03 min ]. Group B+L produced prolonged duration of analgesic ( 6.1 + 2.21) hours than Group B ( 4.4 + 1.21) hours & Group L ( 2.6 + 0.62 ) hours.

**4)** A study to know whether mixing of two local anaesthetic agents and by increasing their concentration would provide early onset of action and long duration of analgesia in landmark guided supraclavicular brachial plexus block was conducted by *Raizada et al.* The study was performed in 3 study groups, each group containing 20 patients. Group 1 - received 30 ml of 1% Lignocaine with Adrenaline, Group 2 - received 10 ml of 1.5% lignocaine and 20 ml of 0.25% Bupivacaine, Group 3 - received 10 ml of 2% lignocaine and 20 ml of 0.5% bupivacaine. Out of the above three groups Group 2 (13.91+5.21 min) and Group 3 (11.25+5.79 min) had faster onset of action than Group 1 (21.17+4.19 min) and long duration of block: Group 1 - 59.2+33.2 min > Group 2 - 486.17+109.3 min < Group 3 - 515.9+138.4 min. Their study concluded that addition of lignocaine to bupivacaine provided early onset and the combination of 2% lignocaine and 0.5% bupivacaine was found to be the best choice for long and emergency operative procedures.

**5)** That mixture of short acting and long acting local anaesthetics are used in daily practice but there is lack of information over the advantages of such mixture was proposed by *Jeff Gadsden et al.* Therefore they performed a study in 64 patients undergoing arthroscopic shoulder surgery in 3 random groups receiving (30ml of 1.5% mepivacaine, 30 ml of 0.5% bupivacaine, mixture of 15ml of 0.5% bupivacaine and 15ml of 1.5% Mepivacaine) to study latency of block onset and duration of analgesia in ultrasound guided Interscalene block. Their study revealed that, under ultrasound guidance the onset of block for the drug mixture 1.5% mepivacaine with 0.5% bupivacaine (11.3+5.3 min) was longer either local anaesthetics 1.5% mepivacaine (8.7 + 4.3 min) &

0.5% bupivacaine (10.0 + 5.1 min) alone. Therefore, mixture of the two local anaesthetic drugs didn't provide any significant change in onset of action. Moreover the duration of analgesia was high in 0.5% Bupivacaine (14.0 + 6.2 hours) than mixture of 1.5% mepivacaine with 0.5% bupivacaine (10.3 + 4.9 hours).

#### 4 RESEARCH HYPOTHESIS

A mixture of lignocaine and bupivacaine provides quicker onset when compared to bupivacaine given alone and prolonged analgesia when compared to lignocaine given alone.

#### 5 SUBJECTS AND METHODS

After obtaining IRC and Ethical committee approval the study will be conducted in Mahatma Gandhi Medical College and Research.

##### Study population

Patients undergoing elective or emergency upper limb bone surgeries in MGMCRI will form our study population.

##### **Inclusion criteria:**

Patients belonging to the age group 18-60 years with ASA grade I and grade II undergoing elective or emergency procedure for upper limb bone surgeries at or below the elbow.

##### **Exclusion criteria:**

1. Patient refusal for the block. Patients refusing the block will be administered general anaesthesia.
2. History of bleeding disorders
3. Local infection at the site of block
4. Pre-existing neurological deficit
5. Cardio-Respiratory compromise.
6. Known allergy to local anesthetic drug.
7. Patients in whom the supraclavicular sono-anatomy is not clear.

### Sample size

“Statistics and Sample Size” App (version 5.0 developed by Thai Thanh Truc) was used to calculate the sample size. In a pilot study in ten patients, we observed that the onset of complete conduction block with drug combination was  $19 \pm 11$  minutes, while with bupivacaine it was  $30 \pm 12$  minutes. With an alpha error of 0.05 and power of 80%, the minimum sample size was estimated to be 18 in each group. To take into account the drop-outs, 63 patients from the study population meeting the inclusion criteria will be recruited.

All consecutive patients posted for upper extremity surgery will be screened for recruitment— continuous sampling.

Patients will be Randomised to any one of the three study groups:

Group LB: Patients receiving 10ml 0.5% bupivacaine + 10 ml 2% lignocaine with adrenaline pre-mixture.

Group L: Patients receiving 20 ml 2% lignocaine with adrenaline premixture.

Group B: Patients receiving 20 ml 0.5% bupivacaine.

Randomization will be done using block randomization technique. Each block will contain 9 envelopes, 3 belonging to each group. Patients were randomized to one of the three study groups: lignocaine- bupivacaine (Group LB), bupivacaine (Group B) or lignocaine (Group L) by drawing sealed envelopes that contained a card with the group name written in it. A resident of anesthesia, who was not involved in the study, will generate the envelopes.

All the blocks will be performed in the procedure room under standard monitoring (electrocardiography, pulseoximetry and non-invasive blood pressure). An 18-gauge IV line will be secured. An IV sedation of 2mg midazolam will be given before the ultrasound procedure. The patient will be positioned with the arms by the side. All blocks will be performed under ultrasound guidance by using high frequency linear probe (HFL50) by one of the two investigators. Patients will be randomly allocated into anyone of the groups by selecting a sealed envelope contain the allocated group.

The drug preparation will be performed by an independent anesthesiology resident blinded to the study. For the bupivacaine group- Group B, 20 ml of 0.5% bupivacaine will be

used for BPB. For the lignocaine-bupivacaine group – Group LB, a combination of 10 ml 2% lignocaine with adrenaline and 10 ml 0.5% bupivacaine will be used for BPB.

For Group L, 20 ml of lignocaine with adrenaline mixture will be used. The study drug will be loaded in 20 ml syringe connected to a 100-centimeter pressure monitoring line and 25-gauge spinal needle.

The brachial plexus will be scanned close to the subclavian artery as a bunch of grapes (Multiple small hypoechoic nodules embedded in a hyper echoic area and encircled by a hyper echoic line). The study drug will be injected subfascial as described previously by the investigators<sup>1</sup>. Adequate spread of local anesthetics will be confirmed by USG imaging. If necessary, the needle will be repositioned for adequate spread. The person performing the block will take no further part in data collection.

#### **Assessment**

After a satisfactory drug deposition, the Final Needle removal will be noted as block time. Since then, the neurological assessment will be done by an Observer blinded to group allocation, every 10 min till 40 minutes.

Sensory Blockade will be assessed on a three-point Qualitative Scale for perseverance of cold sensation to Ether-soaked cotton.

0 - perceives both touch and temperature

1 - perceives only the touch but not the temperature

2 - perceives neither touch nor temperature

Sensory Blockade will be assessed in the territories of Musculocutaneous nerve (MCN) - Lateral forearm, Median Nerve (MN) – Tip of Middle Finger , Ulnar Nerve (UN) – Little Finger and Radial Nerve (RN) – Anatomical snuff box. Score of 2 in all the 4 nerve distribution area will be **taken as time for complete sensory block** .

Motor Blockade will be assessed on a 3 point Qualitative Scale.

0 - Normal Motor Function ( Power 4/5 , 5/5 )

1 - Decreased Motor Function ( Power 3/5 , 2/5 )

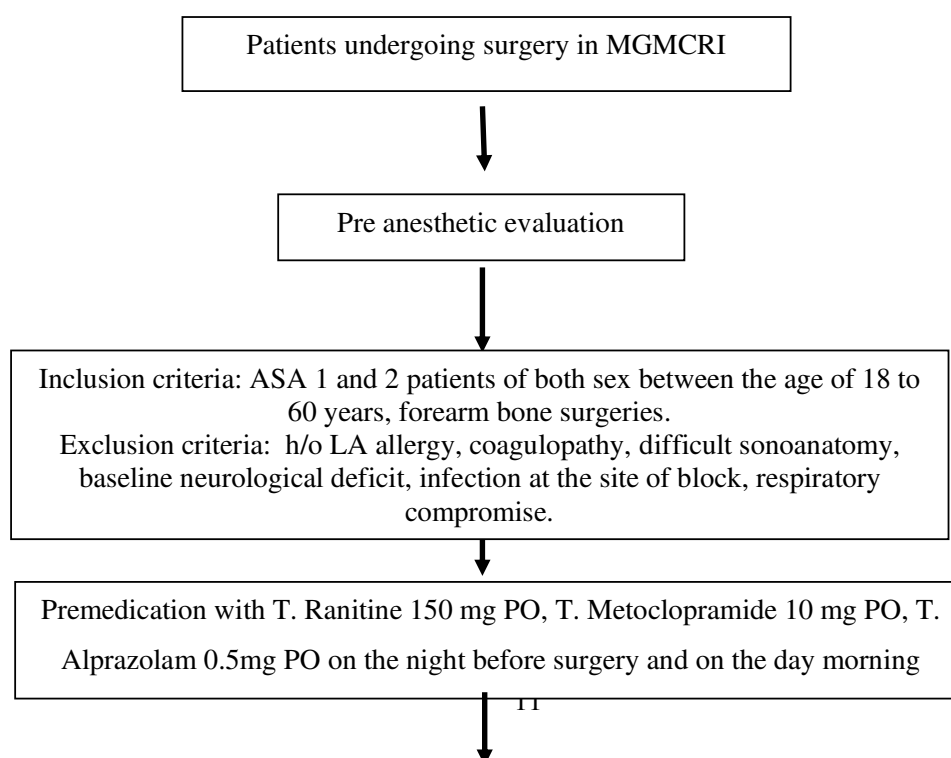
2 - No Motor Power (Power 0/5 , 1/5 )

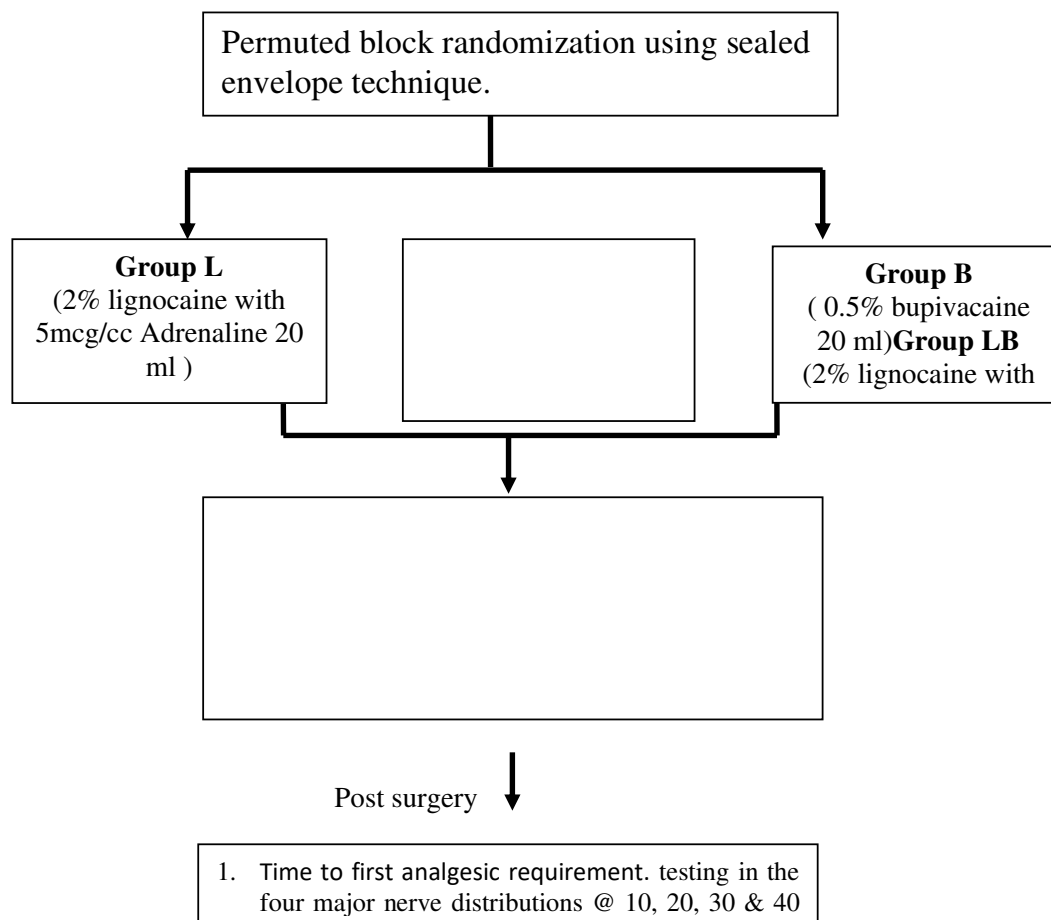
for the Four Terminal Branches (Elbow Flexion - Musculocutaneous Nerve, Thumb Opposition - Median Nerve , Thumb Adduction - Ulnar Nerve , Thumb Abduction- Radial Nerve). Score of 2 in all the 4 nerve distribution area will be taken as **time for complete motor block** .

After starting the surgery if the patient feels discomfort at the surgical site another supplementation of 1mcg/kg Fentanyl will be given intravenously. Block will be considered failed if the patient complains of pain or requires more than 2mcg/kg Fentanyl. Further anesthetic management will be decided by the attending Anesthesiologist.

Inside the operating room, patients will be sedated for comfort before the start of surgery using intravenous midazolam 1 mg and fentanyl 1 µgm/kg. Block will be considered a failure if the patients complained of pain during any stage of surgery or required any form of rescue analgesic interventions. Post-operatively, patients will be instructed to inform when they perceive pain at the surgical site and receive Inj.Acetaminophen 1 gm and ketorolac 30 mg intravenously and subsequently put on regular oral analgesics as per departmental acute pain service protocol. The time gap from Time 0 to the first perception of pain by the patient will be taken as the **duration of analgesia**. 24-hours later, the patients will be questioned for the presence of paresthesia, dysesthesia, or motor weakness in the operated limb

## 5.1 FLOW-CHART TO SUMMARIZE THE SEQUENCE OF EVENTS





## 5.2 STUDYTERMINATION

Study will be terminated once sample size is obtained

## 6 STUDYVARIABLES

S. No	Name of the dependent / independent variables	Scale of measurement (Quantitative / qualitative)	Summarizing data	Statistical test to be used
1	Age	Quantitative	Mean $\pm$ SD	One way ANNOVA
2	Sex	Qualitative	Percentage	Chi square test
3	BMI	Quantitative	Mean $\pm$ SD	One way ANNOVA
4	Type of surgery	Qualitative	Percentage	Chi square test
5	Duration of surgery	Quantitative	Mean $\pm$ SD	One way ANNOVA
6	Time for colmplete sensory block.	Quantitative	Mean $\pm$ SD	One way ANNOVA
7	Time for colmplete motor block.	Quantitative	Mean $\pm$ SD	One way ANNOVA
8	Duration of analgesia	Quantitative	Mean $\pm$ SD	One way ANNOVA
9	% of patients with complete conduction block at 10, 20 and 30 minutes	Quantitative	Percentage	Chi square test
10	Complications (if any)	Qualitative	Percentage	Chi square test



## 7 REFERENCES

1. Sivashanmugam T, Suja Ray, Ravishankar M, Jaya V, Selvam E and Manoj Kumar Karmakar. "Randomized Comparison of Extrafascial Versus Subfascial Injection of Local Anesthetic During Ultrasound-Guided Supraclavicular Brachial Plexus Block." *Regional Anesthesia and Pain Medicine* 2015;4:337–43.
2. Laur, John J, Emine Ozgur Bayman, Peter J. Foldes, and Richard W Rosenquist. "Triple-Blind Randomized Clinical Trial of Time until Sensory Change Using 1.5% Mepivacaine with Epinephrine, 0.5% Bupivacaine, or an Equal Mixture of Both for Infraclavicular Block." *Regional Anesthesia and Pain Medicine* 2012;37: 28–33.
3. Özmen, Özgür, Hacı Ahmet Alici, Mine ÇELİK, Aysenur Dostbil, and Mehmet Cesur. "The Effect of Addition of Lidocaine to Bupivacaine on Anesthesia Beginning Time, Block Time, and Block Quality in Lateral Sagittal Infraclavicular Block." *Turkish journal of medical sciences* 2013; 43 : 542–47.
4. Raizada, N., Jain PC Chandralekha, and A. Kumar. "Does Compounding and Increase in Concentration of Local Anaesthetic Agents Increase the Success Rate of Brachial Plexus Block." *Indian J. Anaesth* 2002;3:193–96.
5. Strichartz G, Berde C. Local anesthetics. In: Miller R, ed. *Miller's anesthesia*, 6th ed. Philadelphia: Elsevier Churchill Livingstone, 2005:573–604
6. Gadsden, Jeff, Admir Hadzic, Kishor Gandhi, Ali Shariat, Daquan Xu, Thomas Maliakal, and Vijay Patel. "The Effect of Mixing 1.5% Mepivacaine and 0.5% Bupivacaine on Duration of Analgesia and Latency of Block Onset in Ultrasound-Guided Interscalene Block." *Anesthesia & Analgesia* 2011;2: 471–76.

## 8 PRELIMINARY WORK DONEALREADY

Pilot study on 10 patients.

## 9 ETHICALISSUES

This study involves humans and requires frequent testing of sensory and motor blockade. Only temperature and light touch is used for sensory assessment.

In case of surgery exceeding block duration, general anesthesia will be administered.

The study falls in the "more than minimal risk" category. Combination of local anaesthetics used in the present study, is regularly used for peripheral nerve blocks.

### **10 INFORMED CONSENT PROCEDURE**

During the preanaesthetic visit, the procedure will be explained to the patient. They will be informed that there are three arms in the study and they will have an equal chance of entering into either arm. This will be explained in their own language and consent will be obtained for including them in the study.

### **11 QUALITY CONTROL**

Name of Officer designated by the department for quality control:  
Dr. VR Hemanth Kumar  
Professor & Head  
Department of anaesthesiology  
9003550553  
drvrhk@gmail.com

### **12 SPONSORSHIPS**

NIL

### 13 INVESTIGATORS DECLARATION

This is to certify that the protocol entitled “ **To determine the latency of three local anaesthetic solutions during ultrasound guided supraclavicular brachial plexus block- A double blind randomized control trial.**” was reviewed by us for submission to the SBV Institutional Ethics Committee and certified that this protocol represents an accurate and complete description of the proposed research. We have read the ICMR guidelines, ICP-GCP guidelines/CPCSEA guidelines/and other applicable guidelines and undertake to ensure that the rights and welfare of the study subjects are protected.

The study will be performed as per the approved protocol only. If any deviation is warranted, the same will be presented to the ethical committee and permission will be sought. We assure that the study will be terminated immediately in case of any unforeseen adverse consequences and we will inform the same to the ethical committee immediately.

	Name	Designation	Signature	Date
Investigator	Dr. Sripriya. R	Professor, Dept. of Anesthesiology		
Co- Investigator	Dr. T. Sivashanmugam	Professor, Dept. of Anesthesiology		

## **Patient/Participant Information Sheet (PIS)**

### **(Information for Participants of the Study)**

We welcome you and thank you for having accepted our request to consider whether you can participate in our study. This sheet contains the details of the study, the possible risks, discomfort and benefits for the participants are also given. You can read and understand by yourself; if you wish, we are ready to read and explain the same to you.

If you do not understand anything or if you want any more details we are ready to provide the details.

#### **1. What is the title of the Research Project?**

**“To determine the latency of three local anaesthetic solutions for ultrasound guided supraclavicular brachial plexus block – A double blind randomized control trial.”**

#### **2. Who /where is this study being conducted?**

This study is being conducted by Dr. SRIPRIYA. R, professor, department of anaesthesiology, MGMCRI

#### **3. What is the purpose of the study?**

Different types of drugs are used around nerves for blocking pain during regional anaesthesia. A few of them start acting fast, but provide short duration of pain relief. A few of these drugs start acting late, but provide long duration of pain relief. By combining them, we get the advantages of either drug used alone. In this study we want to find out the onset of action when a combination of these drugs is used and the duration of pain relief provided by combining them for supraclavicular brachial plexus block. The procedure will be done under ultrasound guidance.

#### **4. Procedure/Methods of the study (in brief, simple non-technical terms)**

In this study one group of patients will be receiving block with a drug that is fast acting. One group of patients will be receiving block with a drug that takes some more time to begin acting. Yet another group will receive a combination of the two drugs. You will have an equal chance of being included in any of the groups. After the injection is done, we will test you at 10 minute intervals to get information on how much time it takes to produce complete loss of sensation and complete loss of

motor power. After that, the surgery will begin. After the surgery is over, we will continue to follow up till you first perceive pain.

**5. How long you are expected to participate in this study?**

We will be visiting you after the surgery is over to get information on when you are beginning to first perceive pain. Once you perceive pain, the time will be noted and we will give you medicines for pain relief. After that the study ends.

**6. Why I am being considered as one of the participant?**

You have been chosen as you are undergoing surgery for forearm bone fracture and this block will give you pain relief both during the surgery and even after the surgery is over.

**7. Should I definitely have to take part in this study?**

No. If you do not wish to participate you will not be included in this study. Also you will continue to get the medical treatment without any prejudice.

**8. If I am participating in this study, what are my responsibilities? (Responsibility of the individual as a participants)**

Being a participants in this study your responsibility are :1. To cooperate during preanesthetic checkup 2. To cooperate when the block action is being checked 3. To inform us when you first perceive pain after surgery is over.

**9. Are there any benefits for me/Public?**

The results of the study may benefit future patients. This study will give us information on whether there is any use in combining these drugs.

**10. Will there be any discomfort / risks to me?**

No risks. But some discomforts may be there. You may have mild pain on the needle insertion. We will be giving medicines at the needle prick site to reduce it. Risk will be the same as for any block.

**11. Will by participating in this study, my personal details will be kept confidentially?**

Your participation in the study and the study records relating to you will be kept confidential throughout the study and thereafter. Your personal identity will not be revealed in case of publication in any journal or analysis of your results, nor will it be

shared with anyone. The study records relating to you will be preserved for a period of three (if academic Research)/ five years (if clinical trial) for analysis and follow up.

**12. Will I be paid for participating in the Study?**

No. you will not be paid for participating in the study.

**13. Can I withdraw from this study at any time during the study period?**

Your participation in the study is purely voluntary. You are free to withdraw from the study at any time without assigning any reason. Your withdrawal from the study would in no way affect the medical care or other benefits which you are otherwise entitled to receive from the Institute

**14. Possible current and future uses of the biological material to be generated from the research and if the material is likely to be used for secondary purposes or would be shared with others, for which we seek your permission prior to the study inclusion?**

Not applicable.

**15. Possible current and futures uses of the data to be generated from the research and if the data is likely to be used for secondary purposes or would be shared with others, for which we seek your permission prior to the study inclusion?**

The data collected from you may be utilized for further analysis in future, if needed. All the data obtained from you will be used only for research purposes. It will not be used for any secondary purpose nor will it be shared with others. In case of analysis of your data in any publication in any journal, your identification will not be revealed.

**16. Will I be informed of this study's results and the findings?**

Yes, on your request the results of the study and its findings you will be informed.

**17. Provision of free treatment for research related injury.**

Not applicable. The procedure and drug used in the study is used routinely for anaesthetic management of patients with fractures of upper limb. Hence no research related injury is involved in the study.

**18. Compensation to the participant for death or disability arising out of foreseeable and unforeseeable risks attributable to the study.**

Not applicable. The procedure and drug used in the study is used routinely for anaesthetic management of patients with fractures of upper limb. Hence no research related injury is involved in the study.

**Address and mobile number of the Principal Investigator (PI) and Co-PI, if any:**

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Office of Institutional Human Ethics Committee, 1<sup>st</sup> floor college block (Adjacent to dept. of Pathology), MGMCRI, Puducherry 607 402. Phone No.: 0413- 2616700 (Extn No.: 754)

Signature of the Participant

Signature of the Investigators

**MAHATMA GANDHI MEDICAL COLLEGE AND RESEARCH INSTITUTE  
PUDUCHERRY**

**FORM FOR GETTING INFORMED CONSENT FOR THOSE PARTICIPATING  
IN THE RESEARCH PROJECT**

**Name of the Research Project**

**“To determine the latency of three local anaesthetic solutions for ultrasound guided supraclavicular brachial plexus block – A double blind randomized control trial.”**

I \_\_\_\_\_ have been informed about the details of the study in own language.

I have understood the details about the study.

I know the possible risks and benefits for me, by taking part in the study.

I understand that I can withdraw from the study at any point of time and even then, I will continue to get the medical treatment as usual.

I understand that I will not get any payment for taking part in this study.

I will not object if the results of this study are getting published in any medical journals, provided my personal identity is not reviewed.

I know what I am supposed to do by taking part in this study and I assure that I will give my full co-operation for this study.

I nominate ----- (name) (mention the relation) to be my dependant to receive compensation if any.

Signature/Thumb impression of the participant  
(Name/Address/Occupation/Monthly income)

\_\_\_\_\_

\_\_\_\_\_

Signature/Thumb impression of the witness (Name/Address)

\_\_\_\_\_

\_\_\_\_\_

Name & Signature of the investigator

\_\_\_\_\_