From:
Dr. **SHAH MESHA SHETALKUMAR**
1st Year PG Resident
Department of Anaesthesiology
Parul Institute of Medical Sciences & Research (PIMSR), Limda
E Mail Id: meshashahh@gmail.com
Mobile No: 6355084827
Date:

To,
Parul University Institutional Ethics Committee for Human Research (PUIECHR),
Parul Institute of Medical Sciences & Research (PIMSR) Limda, Gujarat, India.

Subject: Application for getting permission to carry out research work as a M.D. Anaesthesiology PG Student

Sir / Madam,

I, undersigned **Dr. SHAH MESHA SHETALKUMAR** ,am currently working as a 1st Year PG Resident in Department of Anaesthesiology at Faculty of Medicine under Parul Institute of Medical Sciences & Research (PIMSR). I am applying for M.D. Dissertation permission in the Department of Anaesthesiology, Parul Institute of Medical Sciences & Research (PIMSR), Limda. I want to carry out a research study titled "**Effect of adding magnesium sulphate as an adjuvant to local anaesthetics in supraclavicular brachial plexus block for upper limb surgeries" under guidance of Dr. Sudha Shah, Professor, Department of Anaesthesiology, Parul Institute of Medical Sciences & Research (PIMSR), Limda.**

I am submitting a proposal for the study in the prescribed format along with necessary reference papers, and an assurance letter from the guide. This Study will be conducted strictly as per the ethical guidelines with due consideration of prevention of plagiarism.

Thanking You.

Yours Sincerely,

Dr. **SHAH MESHA SHETALKUMAR**

<u>Enclosures</u>

1. Application Form
2. Assurance Letter of Guide
3. Study Protocol with Study Related Documents
4. Case Report Form, Patient Information Sheet & Informed Consent Form
5. ADR Reporting Form/ Study Tool / Questionnaire
6. Permission of Dean, Parul Institute of Medical Sciences & Research (PIMSR) Limda
7. Permission of Medical Superintendent, Parul Sevashram Hospital, Limda
8. Minutes of Presentation at Department Meeting with Signed Attendance Sheet

Forwarded through Head of the Department

APPLICATION FORM

Title of The Study	**"EFFECT OF MAGNESIUM SULPHATE AS AN ADJUVANT TO LOCAL ANAESTHETICS IN SUPRACLAVICULAR BRACHIAL PLEXUS BLOCK FOR UPPER LIMB SURGERIES"**
Name of The Student	**DR. SHAH MESHA SHETALKUMAR** **M.B.B.S.**
PG Admission Month and Year Branch Name	**February 2025** **M.D. Anaesthesiology**
Name of the Guide & Department	**Dr. SUDHA SHAH** **Designation: Professor** **Department of Anaesthesiology,** **Parul Institute of Medical Sciences & Research.**
Source of funding if any	**No**
Type of Study	**Prospective Study**
Ethical Issues Involved in The Study	**Invasive Procedure: Yes** **Intervention: Yes**
Proposal Enclosed In 8 Copies.	**Yes**
Whether Consent Forms in English & Vernacular Language is Enclosed.	**Yes**
Is this special research?	**Animal Experiment: No** **Clinical Trial: Yes** **Research on Patented Product: No** **Research on Herbal Extract: No**

Signature of the PG Resident:
Dr. SHAH MESHA SHETALKUMAR

Signature of the guide:
Dr. SUDHA SHAH

From:
Dr. **SHAH MESHA SHETALKUMAR**
1st Year PG Resident
Department of anesthesiology
Parul Institute of Medical Sciences & Research (PIMSR),
Limda
Date: / /

To,
The Dean,
Parul Institute of Medical Sciences & Research (PIMSR), Limda, Gujarat, India.

Subject: **Application for getting permission to carry out research work as a M.D. Anaesthesiology Student**

Respected Sir,

I, undersigned **Dr. SHAH MESHA SHETALKUMAR**, am applying for study in the Department of **Anaesthesiology**, Parul Institute of Medical Sciences & Research (PIMSR). I want to carry out a research study titled "**Effect of adding magnesium sulphate as an adjuvant to local anaesthetics in supraclavicular brachial plexus block for upper limb surgeries"** under guidance of **Dr. SUDHA SHAH**, Professor in Department of **Anaesthesiology**, Parul Institute of Medical Sciences & Research (PIMSR), Limda. Kindly give me permission to carry out above mentioned research work.

Thanking You.

Yours Sincerely,

Dr. SHAH MESHA SHETALKUMAR

From:
Dr. SHAH MESHA SHETALKUMAR
Department of Anaesthesiology
Parul Institute of Medical Sciences & Research (PIMSR)Limda
Date: / /

To,
The Medical Superintendent,
PSH & Parul Institute of Medical Sciences & Research (PIMSR),
Limda, Gujarat, India.

Subject: **Application for getting permission to carry out research work as a M.D. Anaesthesiology Post Graduate Resident.**

Respected Sir / Madam,

I, undersigned **Dr. SHAH MESHA SHETALKUMAR,** am applying for study in the Department of Anaesthesiology, Parul Institute of Medical Sciences & Research. I want to carry out a research study titled "**Effect of adding magnesium sulphate as an adjuvant to local anaesthetics in supraclavicular brachial plexus block for upper limb surgeries"** under guidance of **Dr. SUDHA SHAH,** Professor in Department of **Anaesthesiology,** Parul Institute of Medical Sciences & Research (PIMSR), Limda. Kindly give me permission to carry out above mentioned research work.

Thanking You.

Yours Sincerely,

Dr. SHAH MESHA SHETALKUMAR

ASSURANCE LETTER OF GUIDE

Date: / /

To,

Parul University Institutional Ethics Committee for Human Research (PUIECHR),
Parul Institute of Medical Sciences & Research (PIMSR), Limda

Subject: **Assurance for mentoring of Dr. SHAH MESHA SHETALKUMAR for M.D. Study in Department of Anaesthesiology**

Sir/ Madam,

This is to inform you that the research work titled "**Effect of adding magnesium sulphate as an adjuvant to local anaesthetics in supraclavicular brachial plexus block for upper limb surgeries**" will be carried out by **Dr. SHAH MESHA SHETALKUMAR** in the Department of **ANAESTHESIOLOGY**, Parul Institute of Medical Sciences & Research (PIMSR) Limda, under our guidance and observation.

We assure you in this regard that the work will be done strictly as per the ethical guidelines with due consideration of prevention of plagiarism.

Yours Truly,

Dr. SUDHA SHAH

Professor,

Department of **Anaesthesiology**

Parul Institute of Medical Sciences & Research (PIMSR), Limda

STUDY PROTOCOL

NAME OF THE RESEARCHER

Dr. Shah Mesha Shetalkumar (MBBS)

1st year Resident,

Department of Anaesthesiology,

Parul Institute of Medical Sciences & Research(PIMSR) Limda.

NAME OF THE GUIDE AND DEPARTMENT

Dr. Sudha Shah,

Professor of Department of Anaesthesiology,

Parul Institute of Medical Sciences & Research (PIMSR), Limda.

TITLE OF STUDY

EFFECT OF ADDING MAGNESIUM SULPHATE AS AN ADJUVANT TO LOCAL ANAESTHETICS IN SUPRACLAVICULAR BRACHIAL PLEXUS BLOCK FOR UPPER LIMB SURGERIES

INTRODUCTION

Surgical procedures of upper extremities can be performed under regional anaesthesia (peripheral nerve blocks) or under general anaesthesia. Performing surgery under regional anaesthesia is relatively safer and free of risks associated with general anaesthesia. Brachial plexus block (BPB) is being increasingly used as a primary mode of anaesthesia for surgeries of the upper extremity. Its advantages over general anaesthesia include maintaining consciousness, avoiding polypharmacy, better hemodynamic stability, excellent postoperative analgesia and avoidance of postoperative nausea and vomiting [1].

Brachial plexus may be blocked at the level above the clavicle as interscalene and supraclavicular blocks or below the clavicle as infraclavicular and axillary blocks. With increasing attention on patient's safety and better patient outcomes, ultrasound guided regional anesthesia (UGRA) is becoming more widely popular. In our study we have used ultrasound guided supraclavicular technique of brachial plexus block for upper limb surgery [1,2].

Although there are many treatment choices for postoperative pain, a gold standard has not been established. Prolonging the duration of peripheral nerve blocks using long-acting local anaesthetics (LA) or perineural catheters can be used. However, perineural catheters are more time-consuming, costly, have possible higher complication rates (e.g. infection), and need more postoperative care [3].

Several adjuvants such as fentanyl, alpha-2 adrenergic agonists (clonidine or dexmedetomidine), tramadol, and magnesium have been used to extend the duration of peripheral nerve blocks. Magnesium has antinociceptive effects in animal and human models, principally related to blocking the N-methyl-D-aspartate (NMDA) receptors and regulation of calcium influx into cells. Calcium influx leads to a sequence of central sensitization such as windup phenomenon and long term potentiation which are crucial mechanisms that determine the duration and intensity of postoperative pain. Magnesium prevents central sensitization triggered by peripheral nociceptive stimulation in response to painful stimuli [4,5].

We designed this study to evaluate the effect of adding magnesium sulphate to local anaesthetics in the ultrasound-guided supraclavicular brachial plexus block [6,7].

PURPOSE OF THE STUDY

With the advent of ultrasound guidance in regional anaesthesia, various approaches and adjuvants to local anaesthetics in brachial plexus blocks are being increasingly used as an anaesthetic technique for upper limb surgeries. The purpose of this study is to evaluate the effect of adding magnesium sulphate, a universally available and economically viable drug as an adjuvant to local anaesthetics in supraclavicular brachial plexus block for upper limb surgeries using ultrasound guidance in order to identify a possible adjuvant that provides complete surgical anaesthesia with prolonged postoperative analgesia.

OTHER PUBLISHED STUDIES

1.) **The study by M. Selvam et al. (2024),** published in the International Journal of Academic Medicine and Pharmacy (2025; 7(1):760–764), compares the efficacy of bupivacaine alone versus bupivacaine combined with magnesium sulfate in patients undergoing upper limb surgeries under ultrasound-guided supraclavicular brachial plexus block. The research evaluates parameters such as onset and duration of sensory and motor blocks, along with postoperative analgesia. The findings suggest that the addition of magnesium sulfate enhances the quality and prolongs the duration of anesthesia and analgesia without significant side effects, indicating its potential benefit as an adjuvant in regional anesthesia.

2.) Irfan Khan[1], Neelam Tandon[2], Manmohan Jindal[3], and Kushal Jethani[4] conducted a randomized comparative study, published on February 1, 2023, assessing the efficacy of magnesium sulfate versus fentanyl as adjuvants to ropivacaine in supraclavicular brachial plexus blocks for postoperative analgesia in upper limb surgeries. The patients were randomized into two groups: one receiving ropivacaine with magnesium sulfate and the other with ropivacaine and fentanyl. The study found that adding magnesium sulfate significantly improved both the onset and duration of sensory and motor blockade, and provided longer postoperative pain relief compared to the fentanyl group. Hemodynamic parameters remained stable in both groups, with no notable increase in side effects. The authors concluded that magnesium sulfate is a superior adjuvant to fentanyl when combined with ropivacaine for enhancing analgesic efficacy in supraclavicular blocks.

3.) In the study by **Suresh P and Emani A**, titled "Effect of two different dosages of adjunct magnesium sulfate on interscalene nerve blockade: A double blind randomized controlled trial", published in the Indian Journal of Clinical Anaesthesia (2022;9(1):56–59), the authors investigated the efficacy of magnesium sulfate as an adjuvant in interscalene brachial plexus blocks. This double-blind randomized controlled trial compared two different dosages of magnesium sulfate added to local anesthetic in patients undergoing upper limb surgeries. The study found that higher doses of magnesium sulfate significantly prolonged the duration of sensory and motor blockade and enhanced postoperative analgesia without notable adverse effects. The findings suggest that magnesium sulfate, particularly at a higher dose, is a beneficial adjuvant in interscalene nerve blocks for improving block characteristics and analgesic quality.

4.) The study by **Sadafule NN, Deshpande J, and Patil K. (2022)** investigates the comparative effects of perineural versus intravenous administration of magnesium sulfate as an adjuvant to bupivacaine in ultrasound-guided supraclavicular brachial plexus block. The research focuses on evaluating onset time, duration of sensory and motor block, and overall analgesic efficacy. Results indicate that perineural magnesium sulfate offers superior block characteristics and prolonged postoperative analgesia compared to its intravenous counterpart, suggesting its greater effectiveness as an adjuvant in regional anesthesia. The study is published under the Creative Commons Attribution-NonCommercial 4.0 International License.

5.) **Eid SM, Aboul Ella SK, El-Ozairy HSE, Naser TA.** Effect of adding magnesium sulfate to bupivacaine in supraclavicular brachial plexus block in upper limb surgeries.QJM.2021;114(Suppl1):hcab086.doi:10.1093/qjmed/hcab086.100.studied the effect of adding magnesium sulfate to bupivacaine in supraclavicular brachial plexus blocks for upper limb surgeries. Their results showed that magnesium sulfate significantly prolonged the duration of sensory and motor block, enhanced postoperative analgesia, and reduced analgesic consumption without increasing complications, supporting its use as an effective adjuvant.

6.) **Abo El-Hussein AK, Ahmed MA, and Sadek MK** conducted a prospective, randomized, double-blind, placebo-controlled trial published in Minia Journal of Medical Research (2020;31(4):28–32) to evaluate the effects of adding two different doses of magnesium sulfate to 0.5% bupivacaine in ultrasound-guided supraclavicular brachial plexus blocks for upper limb surgeries in ASA I–II adults aged 18–40. Sixty patients were divided into three groups: Group A received bupivacaine alone, Group B received bupivacaine with 100 mg magnesium sulfate, and Group C received bupivacaine with 50 mg magnesium sulfate . The study found that both magnesium doses significantly reduced the time to complete sensory and motor block, prolonged block duration, delayed the first request for postoperative analgesic, lowered total analgesic requirements, and resulted in lower VAS pain scores up to 12 hours postoperatively—especially notable in the 100 mg group—with stable hemodynamic profiles and minimal side effects . The authors concluded that even low-dose (50–100 mg) magnesium sulfate is an effective, safe, and cost-efficient adjuvant to bupivacaine in supraclavicular blocks.

7.) **Ghali AM, Molokhia KM, and Ahmed SA (2019)** conducted a study published in the International Journal of Anesthesia and Clinical Medicine to evaluate the impact of adding magnesium sulfate to bupivacaine in ultrasound-guided supraclavicular brachial plexus block for upper limb surgeries. The study assessed outcomes such as onset time, duration of sensory and motor blockade, and quality of postoperative analgesia. The results showed that the addition of magnesium sulfate significantly shortened the onset time and prolonged the duration of both sensory and motor blocks. Furthermore, it enhanced postoperative pain relief without notable adverse effects. The authors concluded that magnesium sulfate is an effective and safe adjuvant to bupivacaine in improving the efficacy of supraclavicular brachial plexus block anesthesia.

RATIONALE AND GOAL OF THE STUDY

Performing surgery under regional nerve block is relatively safer and free of risks associated with general anaesthesia as it provides good operative conditions, early mobilisation and postoperative analgesia. However, the relatively short duration of local anesthetics often leads to significant postoperative pain once the block wears off. Effective postoperative analgesia improves a patient's outcome in terms of early ambulation, decreased complications, and reduced incidence of postoperative chronic pain.

Hence the main goal of our study is to observe the effect of $MgSO_4$ added to local anaesthetics in the Supraclavicular brachial plexus block in terms of block characteristics, quality and duration postoperative analgesia.

AIM

To compare the onset, duration,block characteristics and quality and duration of postoperative analgesia in patients receiving supraclavicular brachial plexus block with Local anaesthetics alone versus local anaesthetics with magnesium sulfate.

OBJECTIVES

The present study will be undertaken to compare two study groups with the following objectives.

(1) Onset and duration of the sensory block
(2) Onset and duration of the motor block
(3) Duration and quality of Analgesia

MATERIAL AND METHOD

ETHICAL COMMITTEE PERMISSION

After getting permission from The Parul University Institutional Ethics Committee for Human Research (PUIECHR) to carry out this study, first patient will be enrolled / pilot study will be carried out.

METHODOLOGY

- This study will be conducted in the Department of Anaesthesia, Parul Institute of Medical Sciences and Research (PIMSR), Gujarat, India following Ethical Committee approval for a period of 1.5 years or till sample size is completed.
- 70 Patients between the age of 18-70 years undergoing supraclavicular brachial plexus block, willing to give consent and belonging to ASA (American Society of Anesthesiologists) Grade 1 and 2 will be selected.
- There will be 2 groups of 35 each- **GROUP C** and **GROUP M,** receiving bupivacaine - xylocaine with adrenaline mixture with or without $MgSO_4$ respectively.

PRE-OPERATIVE MANAGEMENT

- All patients meeting inclusion criteria will undergo thorough preanesthetic check up. Patients will be evaluated for any past or present systemic diseases and their treatment. Standard laboratory investigations will be carried out. Our plan of anaesthesia (Supraclavicular brachial plexus block) will be explained to them in simple language.
- Patients will again be re-evaluated one day prior to the surgery as well as outside operation theatre on the day of surgery.
- The procedure of regional anesthesia and the nature of study will again be explained to the patients in their native language.
- The Visual Analog Scale (VAS) scoring system will be explained to the patients and relatives and we will educate them on how we are going to use it and how they are expected to score their pain, with 0 as “NO PAIN” and 10 denoting “WORST PAIN IMAGINABLE”.
- All patients will be kept fasting for 8 hours preoperatively. An intravenous line (18 or 20 G) will be secured on the non operative limb and baseline vitals will be recorded in the preoperative holding area and IV antibiotics will be given before shifting to the operation theatre.

INTRAOPERATIVE MANAGEMENT:

After shifting patient to operation table, baseline vital signs will be recorded i.e. Heart rate (continuous ECG), Blood pressure (systolic, diastolic and mean (MAP)), Respiratory rate (RR), Peripheral arterial Oxygen Saturation (SpO2).
They will be premedicated with injection Glycopyrrolate 0.004 mg/kg + Inj. Ondansetron 0.1 mg/kg + Inj. Midazolam 1 mg prior to the block. Following resuscitation equipments will be kept ready-
A.) Fully equipped Anaesthesia workstation with oxygen and air supply.
B.)Airway,
C.) Laryngoscope,
D.) Proper sized Endotracheal tube,
E.) Breathing circuit,
F.) Ambu bag
G.) Emergency drugs for resuscitation.

Patients will be randomly assigned to one of two groups (35 patients each).
Group C (control) will receive 15 ml of 0.5% bupivacaine + 12.5 ml 2% Xylocaine with adrenaline + 2.5 mL normal saline.
Group M (magnesium) will receive 15 ml of 0.5% bupivacaine + 12.5 ml 2% Xylocaine(2%) with adrenaline + 2.5 mL (250 mg) $MgSO_4$.
All study solutions will be prepared in identical syringes by an anesthesia staff member not involved in patient care; both the patient and the observer will be blinded to group allocation.

$MgSO_4$ solution for adjuvant purpose will be prepared as follows:

- 1 $MgSO_4$ ampoule contains 500 mg/ml of $MgSO_4$
- 1 ml (500 mg) will be taken and diluted upto 10 ml Normal Saline, so each ml contains 50 mg. 2.5 ml (250mg) of this solution will be added to local anaesthetic mixture for Group M.

All patients will receive standard monitoring (ECG, NIBP, SpO_2) and will be positioned supine with the head turned to the opposite side of the limb to be operated upon. A pre-procedure scan will be carried out to note any unexpected anomalies. An ultrasound-guided supraclavicular block will be performed using a high-frequency linear probe.

TECHNIQUE:

After skin asepsis and local infiltration, all participants will receive a supraclavicular brachial plexus block under ultrasound guidance. The patient is positioned supine with the head turned away from the side of the block and operative arm by the side. Using a high-frequency linear ultrasound probe placed in the supraclavicular fossa, the brachial plexus is identified lateral and superior to the subclavian artery. A 23G needle is inserted in-plane from lateral to medial, directed towards the "corner pocket" (The area between the first rib and subclavian artery). After negative aspiration, 10 ml of study drug mixture will be injected. The needle is then slowly withdrawn and redirected to ensure spread around all divisions of the plexus and to avoid intravascular injection. The nerve bundles typically appear as grape- like hypoechoic nodules on ultrasound, and complete spread of the anesthetic is confirmed by circumferential distribution around these structures.

EVALUATION

SENSORY BLOCK

Sensory block will be evaluated every 5 minutes for 30 minutes of block by loss of pinprick sensation with 20G sterile needle and comparing with the sensation in the contralateral limb as follows:

Median Nerve- palmar surface of lateral 3 digits.

Ulnar Nerve – Medial side of wrist and little finger

Musculocutaneous Nerve – lateral side of forearm.

Radial Nerve – Posterior region of Forearm.

The observation will be classified as follows:

Grade 0 – No response to pinprick

Grade 1 – Reduced sensation

Grade 2 – Normal sensation

ONSET OF SENSORY BLOCK (in minutes) will be taken as the time interval between withdrawal of needle after block performance to achieving Grade 0 in all 4 nerve territories.
DURATION OF SENSORY BLOCK will be considered as between onset of sensory block till grade 1 recovery in any one of the 4 territories.

MOTOR BLOCK

Motor block assessment will be done every 5 minutes over a 30 min period beginning from completion of the study drug injection.
Motor block will be evaluated as following:
Grade 0 : Inability to move the forearm, wrist, and fingers,
Grade 1 :Ability to flex or extend only the fingers,
Grade 2 :Ability to flex or extend the wrist and fingers, and
Grade 3 :Ability to flex and extend the forearm.

ONSET OF MOTOR BLOCK (in minutes) will be taken as the time interval between withdrawal of needle after block performance to achieving grade 0.
DURATION OF MOTOR BLOCK will be taken as the time interval from grade 0 of motor block to recovery to grade 3.

Surgery will be allowed to proceed when sensory and motor blocks are Grade 0.

Failure will be defined as surgical anaesthesia not present after 30 minutes of block intervention, need for block supplementation or conversion of block to general anaesthesia during surgery.

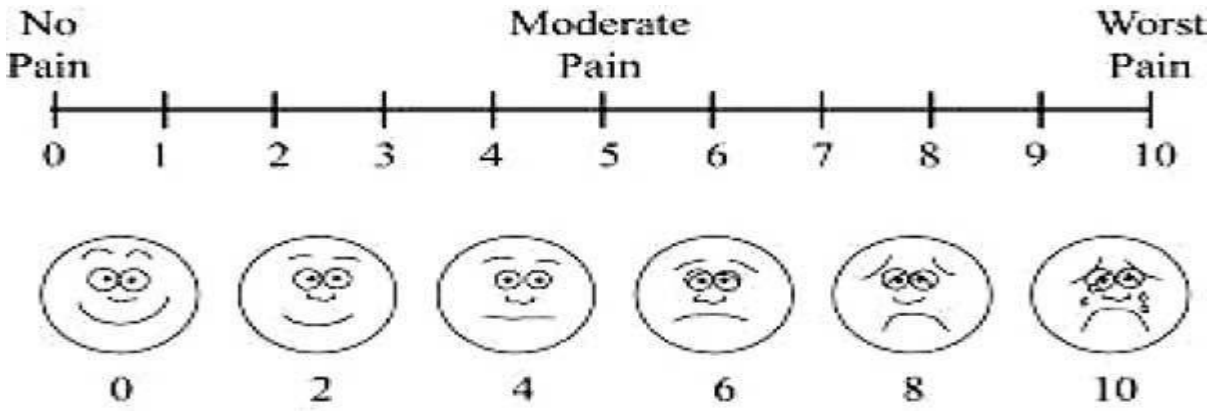
COMPLICATIONS

Patients will be subjected to full standard monitoring. They will be observed for hemodynamic stability , systemic local anaesthetic toxicity, accidental vascular puncture during procedure, accidental intravascular injection of anaesthetic solution, symptomatic pneumothorax , symptomatic hemi diaphragmatic paralysis, post-operative nausea and vomiting (PONV) and any other complications.

Patients will be continuously observed for the following parameters- Heart Rate, Blood Pressure, Spo2, Respiratory rate will be recorded every 5 minutes till 30 minutes then after 30 minutes they will be recorded every 30 minutes till 2 hours (120 minutes) and then every hour for another 2 hours.

POST OPERATIVE ASSESSMENT

- When the surgery will be completed, the patient will be shifted to the recovery room.
- VAS Score will be measured at 0, 1, 3, 6, 9, 12 hours.
- Postoperative pain at the surgical site will be assessed using a 10-point (VAS 0= no pain and 10 = worst imaginable pain), and at a score of >=3, patients will be given injection diclofenac 1 mg/kg in 100 ml Normal Saline (NS) IV and study will be terminated at this point.



STUDY SITE

Department of Anaesthesia, Parul Sevashram Hospital, Parul Institute of Medical Sciences and Research (PIMSR), Limda, Waghodiya, Vadodara.

STUDY POPULATION

Patients aged 18-70 years of age of American Society of Anaesthesiology grade I/II, fulfilling our inclusion criteria, admitted at PSH will be included in our study.

STUDY DESIGN

Prospective, Observational study

SAMPLE SIZE

To estimate the sample size, the difference in block onset time was analyzed from the previously published studies. The data suggests that the estimated difference in the two groups was 1.77 (mean 1= 11.7, mean2= 13.47) with respective standard deviations of 1.1 and 2.07. On the basis of this the sample size estimated at 5% level of significance and 80% power was found to be 6 each but because of good availability of study subjects we increased it to 35. So we decided that we will take a total of 70 patients (35 patients in each group).

INCLUSION CRITERIA

- Patients willing to sign Informed written Consent
- Patients aged 18-70 years of both sexes.
- Patients belonging to American Society of Anesthesiology (ASA) Grade I/II
- Patients posted for elective upper limb surgeries below midarm.

EXCLUSION CRITERIA

- Patients not willing to sign Informed written Consent
- Allergy to local anaesthetic agents
- Infection at the puncture site
- Severe obstructive/Restrictive lung disease
- Preoperative sensory or motor deficits of upper limbs.
- Patient with traumatic / pre- existing nerve injury in the limb to be operated on and clavicular fracture in the operative limb.
- Patient with bilateral Upper limb fractures
- Patient with psychiatric disorders
- Pregnant and lactating female
- Emergency surgery
- Morbid obesity
- Patients with Coagulopathy
- Patients under ASA Grade III and IV

STATISTICAL ANALYSIS METHOD AND TOOL/SOFTWARE

- Statistical Analysis will be performed using IBM-SPSS software and MSExcel software.
- Gender and complications of patients will be presented as numbers and will be compared among groups using Chi square test.
- Age, Weight, Mean HR, Blood pressure, and the time for Scanning Block performance, Onset of block and VAS score will be summarized in the form of Mean ± SD. A p value < 0.05 will be considered statistically significant.
- For Statistical tests, we check normality of data with KS test and if data is normally distributed, a large sample Z test will be used to find out the difference between two means and if data is skewed, Mann Whitney's U test will be used to find out the difference in between median time.

PROPOSED ADVANTAGE OF THIS STUDY

The main advantage of the present study is that ultrasound guidance will provide improved accuracy and safety due to the direct visualisation of target structures, visualisation of the needle and spread of the local anaesthetic drug after injection and hence improve precision. We will be using a drug (magnesium sulphate) which is a very old, versatile, easily available, under no drug controls, economically more feasible option compared to other adjuvants.

ETHICAL CONSIDERATIONS

- Written informed consent from all patients will be obtained a day prior to surgery.

- Permission will be taken from the Ethical Committee before conducting the study.

- All the drugs and techniques used in our study are routinely used.

- Patients are not expected to bear any cost for the purpose of study nor will they be offered any incentive to influence their information.

- Patient privacy, dignity, anonymity and confidentiality will be respected at all times. Any publication will be done or photographs taken/published only after explicit patient /designated representative consent

- Any change in the methodology will be informed to the Ethical Committee.

- On finding of any adverse reaction or side effects in the participating patients, it will be brought to the attention of the Ethical Committee.

- Patients will not be subjected to any harm whatsoever.

REFERENCES

1.) **M. Selvam[1], A. Revathy[2], D. Sasikumar[3], H. M. Hajashareef[4], S. Saravanakumar[5].** Comparative study of bupivacaine with magnesium sulfate and bupivacaine in patients undergoing upper limb surgeries under ultrasound-guided supraclavicular brachial plexus nerve block; 10th Feb 2024. Int J Acad Med Pharm 2025; 7 (1); 760-764

2.) **Irfan Khan[1], Neelam Tandon [2], Manmohan Jindal[3], Kushal Jethani[4];** To evaluate the efficacy of magnesium sulfate and fentanyl as an adjuvant to ropivacaine in supraclavicular brachial plexus block for post-operative pain relief in upper limb surgeries: A comparative randomized study; 1st Feb 2023; http://nepjol.info/index.php/AJMS

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4.) **Sadafule NN, Deshpande J, Patil K.** Comparing the effects of perineural magnesium sulphate with intravenous magnesium sulphate as an adjuvant to bupivacaine in USG-guided supraclavicular block. 2022. Available from: https://creativecommons.org/licenses/by-nc/4.0/

5.) **Eid SM, Aboul Ella SK, El-Ozairy HSE, Naser TA.** Effect of adding magnesium sulfate to bupivacaine in supraclavicular brachial plexus block in upper limb surgeries.QJM.2021;114(Suppl1):hcab086. doi:10.1093/qjmed/hcab086.100.

6.) **Abo El-Hussein AK, Ahmed MA, Sadek MK.** The effect of adding different doses of magnesium sulphate to bupivacaine in ultrasound-guided supraclavicular brachial plexus block anesthesia. Minia J Med Res. 2020;31(4):28–32.

7.) **Ghali AM, Molokhia KM, Ahmed SA**. The effect on the outcome of adding magnesium sulphate to bupivacaine in the ultrasound-guided supraclavicular brachial plexus block anaesthesia. Int J Anesth Clin Med 2019;7:13.

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11.) **Swami SS, Keniya VM, Ladi SD, Rao R.** Comparison of dexmedetomidine and clonidine (α2 agonist drugs) as an adjuvant to local anaesthesia in supraclavicular brachial plexus block: A randomised double-blind prospective study Indian J Anaesth. 2012;56:243–9

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13.) **Swain A, Nag DS, Sahu S, Samaddar DP.** Adjuvants to local anesthetics: Current understanding and future trends. World J Clin Cases. 2017 Aug 16;5(8):307-323. doi: 10.12998/wjcc.v5.i8.307. PMID: 28868303; PMCID: PMC5561500.

CASE REPORT FORM

PRE-ANAESTHETIC EVALUATION

NAME: Date of Admission:
AGE / SEX: Date of Operation:
IPD NO: Height:
Diagnosis: Weight:
Surgery:
Present history:
Past history:
Personal history:

GENERAL PHYSICAL EXAMINATION

General condition :
Pallor :
Icterus :
Cyanosis :
Edema :
Lymphadenopathy :

VITALS

Temperature :
Pulse : ____ / min
Spo2 : _____ %
Blood pressure : ____mmhg
RR : _____ / min

AIRWAY ASSESSMENT

Mouth opening :
Teeth :

MPG :
Head and neck movement: 1. Flexion
2. Extension
3. Lateral rotation
Back and spine :

SYSTEMIC EXAMINATION:

Respiratory system :
Cardiovascular system :
Central Nervous system:
Per Abdomen:

RELEVANT LABORATORY INVESTIGATIONS

CBC :
Coagulation profile :
RBS :
Blood urea :
Serum creatinine :
SGOT :
SGPT :
Serum electrolytes :
Total bilirubin :
Direct bilirubin :
Indirect bilirubin :
HIV, HbsAg, HCV :
Chest X-RAY :
ECG :
2D Echo :

Patient is taken under ASA GRADE. : _____
Advice : _____
_____
Supraclavicular Brachial Plexus Block given at: _____ (time)

Patients will be divided into two groups:
Group C: 15 ml of 0.5% bupivacaine + 12.5 ml 2% Xylocaine(2%) with adrenaline + 2.5 ml normal saline.
Group M: 15 ml of 0.5% bupivacaine + 12.5 ml 2% Xylocaine(2%) with adrenaline + 2.5ml (250 mg) $MgSO_4$.

4. **Assessment of Sensory block**:

Grade 0 – No response to pinprick

Grade 1 – Reduced sensation

Grade 2 – Normal sensation

- Onset of sensory block (GRADE 0) at ____ (time)
- End of sensory block (GRADE 1) at_____ (time)
- Total duration of sensory block:___Hrs_____Min

5. **Assessment of Motor block** :

Grade 0 : Inability to move the forearm, wrist, and fingers,
Grade 1 :Ability to flex or extend only the fingers,
Grade 2 :Ability to flex or extend the wrist and fingers, and
Grade 3 :Ability to flex and extend the forearm.

- Onset of motor block (GRADE 0) at _____(time)
- End of motor block (GRADE 3) at ___(time)
- Total duration of motor block: ____Hrs_____Min

6. Duration of surgery : _____ Hrs

INTRAOPERATIVE HAEMODYNAMIC PARAMETERS

	0 min	5 min	10 min	15 min	20 min	25 min	30 min	60 min	90 min	120 min	180 min	240 min
HR (bpm)												
Systolic BP (mmhg)												
Diastolic BP (mmhg)												
SPO2 (%)												

Assessment of complications:

- Hypotension
- Bradycardia
- Shortness of breath
- Mild sedation
- Signs of LAST (Local Anaesthetic Systemic Toxicity)

POST OPERATIVE OBSERVATION

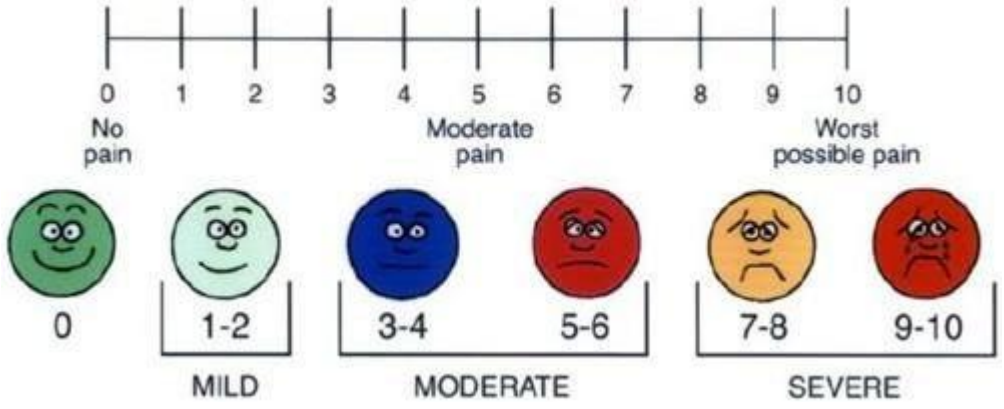
	GROUP C	GROUP M
1.) Duration of sensory block		
2.) Duration of motor block		
3.) VAS Score		

0 hr		
1 hr		
3 hr		
6 hr		
9 hr		
12 hr		

ASSESSMENT OF PAIN:

The most important parameter of the study

VAS SCORING SYSTEM



Time of giving Injection Diclofenac 1 mg/ kg IV in 100 ml Normal Saline (when VAS score >=4): _____ (time)

Duration of analgesia: _____ Hrs ____Min

PATIENT INFORMATION SHEET AND INFORMED CONSENT FORM (Vernacular Language)

STUDY NO: DATE:

TITLE OF THE STUDY: Effect of adding magnesium sulphate as an adjuvant to local anaesthetics in supraclavicular brachial plexus block for upper limb surgeries

INTRODUCTION

You are cordially invited to participate in the above titled study. The proposed study is a scientific endeavor to generate data on the effect of the drug (Mgso4) in the supraclavicular brachial plexus block technique and thus keeping you conscious avoiding the need for general anaesthesia. In case you have any problems during the surgery, you will be able to talk to us.

1. **What is the purpose of this study?**
   The purpose of this study is to check the effect of the drug (Mgso4) in the supraclavicular brachial plexus block so as to provide better anaesthesia and cause least discomfort to you.

2. **Why have I been chosen?**
   You have been chosen because you meet our required criteria to carry out our study.

3. **Do I have to take part?**
   Your participation is voluntary. You can also refuse to take part in the study. Moreover, you are also free to withdraw your consent at any time during the study without having to give a reason. Despite this, you shall be given all the medical care and treatment that you are entitled to.

4. **How long will the study last?**
   The study involves observation and monitoring for upto 12 hours after the injection.

5. **What will happen to me if I take part?**
   The study is purely observational. This will not interfere with your surgical treatment. Your surgical treatment will be decided by your surgeon. As part of the anaesthetic procedure, you may receive a prick above your collarbone through which anaesthetic drug will be injected to numb your arm. You will be awake throughout the procedure but you will not feel any pain. You may be asked a few questions relevant to this study by an investigator and which will be recorded in the Case report form.

6. **What do I have to do?**
   Understand the procedure, sign the informed consent and cooperate during the study till the end. You may need to share information regarding the study with the investigator as and when necessary.

7. **What are the benefits of the study?**
   You will receive a comfortable and least painful technique to anaesthetise your arm and get consistent and prolonged duration of analgesia. We will be able to avoid general

anaesthesia and its related risks and complications.

8. What are the side effects of the treatment received during the study?

During the study, medicines like bupivacaine, magnesium sulphate, and xylocaine with adrenaline will be used. Some patients may experience mild side effects such as allergic reaction and low blood pressure. All side effects will be carefully monitored and managed promptly if needed.

9. What if new information becomes available?

If there will be new information available regarding the study, we will follow the new guidelines and also inform you. We also have to inform our committee which always protects your safety and interest.

10. What happens when the study is complete?

When the study is completed, we will compile the data and statistically analyse the effect of the concerned techniques. It will in no way affect your treatment and follow up.

11. Will the patient taking part be kept confidential?

Yes, your information will be kept confidential and will not be revealed to a third party and shall not be published anywhere without your permission. Your identity shall not be revealed at any time.

12. What about the cost of the drug involved?

You will not have to bear any extra cost for the purpose of this study and no charges apart from the usual anaesthesia charges will be borne by you. You will not get any financial incentive for participating in the study.

13. Is there anything else I should know about the study?

You should be assured that the drugs and the techniques that we will be using in the study have all been well established, with documented safety profiles and minimal side effects.

14. Who to call in case of any query?

If you need any additional information with regard to the study, or if you require any clarification for any doubt, you are free to ask questions to the investigator. You will be given a copy of this participant information sheet for your information and record. However, if you need any further details, you may call the investigator.

Dr. Mesha Shetalkumar Shah
E-mail: meshashahh@gmail.com
Mobile no.: +91 6355084827

દર્દી માહિતી પત્રક અને માહિતીપ્રદ સંમતિ ફોર્મ (સ્થાનિક ભાષા)

અભ્યાસ નંબર: **તારીખ**:

અભ્યાસનું શીર્ષક:
ઉપલા અંગોની શસ્ત્રક્રિયા માટે સુપ્રાક્લેવિક્યુલર બ્રેકિયલ પ્લેક્સસ બ્લોકમાં સ્થાનિક એનેસ્થેટિક્સમાં સહાયક તરીકે મેગ્નેશિયમ સલ્ફેટ ઉમેરવાની અસર

પરિચય:

ઉપરોક્ત શીર્ષકવાળા અભ્યાસમાં ભાગ લેવા માટે આપને હાર્દિક આમંત્રણ છે. પ્રસ્તાવિત અભ્યાસ એ સુપ્રાક્લેવિક્યુલર બ્રેકિયલ પ્લેક્સસ બ્લોક ટેકનિક પર દવા (Mgso4) ની અસર અંગે મહિતી ભેગી કરવાનો અને આમ તમને સંપૂર્ણપણે બેભાન કરવાની જરૂરિયાત ટાળવા માટેનો એક વૈજ્ઞાનિક પ્રયાસ છે. જો તમને શસ્ત્રક્રિયા દરમિયાન કોઈ સમસ્યા હોય, તો તમે અમારી સાથે વાત કરી શકશો.

1.) **આ અભ્યાસનો હેતુ શું છે?**

આ અભ્યાસનો હેતુ સુપ્રાક્લાવિક્યુલર બ્રેકિયલ પ્લેક્સસ બ્લોક પર દવા (Mgso4) ની અસર તપાસવાનો છે જેથી તમને વધુ સારી રીતે સંવેદન મુક્ત થઈ શકો અને તમને ઓછામાં ઓછી અગવડતા થાય.

2.) **મને શા માટે પસંદ કરવામાં આવ્યો છે?**

તમને પસંદ કરવામાં આવ્યા છે કારણ કે તમે અમારા અભ્યાસ હાથ ધરવા માટે અમારા જરૂરી માપદંડોને પૂર્ણ કરો છો.

3.) **શું મારે ભાગ લેવો પડશે?**

તમારી ભાગીદારી સ્વૈચ્છિક છે અને તમે તમારી ઈચ્છા મુજબ અભ્યાસમાં ભાગ લઈ શકો છો. તમે અભ્યાસમાં ભાગ લેવાનો ઈનકાર પણ કરી શકો છો. વધુમાં, તમે કોઈ પણ કારણ આપ્યા વિના અભ્યાસ દરમિયાન કોઈપણ સમયે તમારી મંજૂરી પાછી ખેંચી શકો છો. આ હોવા છતાં, તમને બધી તબીબી સંભાળ અને સારવાર આપવામાં આવશે જેના તમે હકદાર છો.

4.) **અભ્યાસ કેટલો સમય ચાલશે?**

આ અભ્યાસમાં ઈન્જેક્શન પછી 12 કલાક સુધી નિરીક્ષણ અને દેખરેખનો સમાવેશ થાય છે.

5.) **જો હું ભાગ લઈશ તો મારું શું થશે?**

આ અભ્યાસ સંપૂર્ણપણે નિરીક્ષણાત્મક છે. આ તમારી સર્જિકલ સારવારમાં દખલ કરશે નહીં. તમારી સર્જિકલ સારવાર તમારા સર્જન દ્વારા નક્કી કરવામાં આવશે. એનેસ્થેટિક પ્રક્રિયાના ભાગ રૂપે, તમને તમારા હાંસડી ઉપર એક ઈન્જેક્શન અપીશુ જેના દ્વારા તમારા હાથને સુન્ન કરવા માટે દવા અપાશે. તમે સમગ્ર પ્રક્રિયા દરમિયાન જાગૃત રહેશો. તપાસકર્તા દ્વારા તમને આ અભ્યાસ સાથે સંબંધિત કેટલાક પ્રશ્નો પૂછવામાં આવી શકે છે અને તે તેને કેસ રિપોર્ટ ફોર્મમાં રેકોર્ડ કરી શકે છે.

6.) **મારે શું કરવું જોઈએ?**

પ્રક્રિયાને સમજો, જાણકાર સંમતિ પર સહી કરો અને અભ્યાસ દરમિયાન અંત સુધી સહકાર આપો. જ્યારે પણ જરૂરી હોય ત્યારે તમારે તપાસકર્તા સાથે અભ્યાસ સંબંધિત માહિતી ની આપલે કરવાની જરૂર પડી શકે છે.

7.) **અભ્યાસના ફાયદા શું છે?**

સુપ્રાક્લેવિક્યુલર બ્રેકિયલ પ્લેક્સસ બ્લોક માટે લિગ્નોકેઈન અને બ્યુપીવાકેઈન નામના સ્થાનિક એનેસ્થેટિક દ્રાવણ મેગ્નેશિયમ સલ્ફેટ (MgSo4) સાથે/ વગર ઉપયોગ કરવામાં આવે તો, કોઈપણ મોટી આડઅસરો પેદા કર્યા વિના, તમને તમારા હાથને ઓછામાં ઓછી પીડાદાયક રીતે સુન્ન કરવાની અને લાંબા સમય સુધી સંવેદના મુક્તિની રીત મળશે.

8.) **અભ્યાસ દરમિયાન મળેલી સારવારની આડઅસરો શું છે?**

અભ્યાસ દરમિયાન, બ્યુપીવાકેઈન, મેગ્નેશિયમ સલ્ફેટ અને એડ્રેનાલિન સાથે ઝાયલોકેઈન જેવી દવાઓનો ઉપયોગ કરવામાં આવશે. કેટલાક દર્દીઓને એલર્જીક પ્રતિક્રિયા અને બ્લડ પ્રેશર ઓછું થવું જેવી હળવી આડઅસર થઈ શકે છે. આડઅસરનું કાળજીપૂર્વક નિરીક્ષણ કરવામાં આવશે અને તાત્કાલિક દવાથી યોગ્ય સારવાર કરવામા આવશે.

9.) **જો નવી માહિતી ઉપલબ્ધ થશે તો શું થશે?**

જો અભ્યાસ સંબંધિત નવી માહિતી ઉપલબ્ધ હશે તો અમે નવી માર્ગદર્શિકાને અનુસરીશું અને તમને પણ જાણ કરીશું. અમારે અમારી સમિતિને પણ જાણ કરવી પડશે જે હંમેશા તમારી સુરક્ષા અને હિતોનું રક્ષણ કરે છે.

10.) **અભ્યાસ પૂર્ણ થયા પછી શું થશે?**

અભ્યાસ પૂર્ણ થયા પછી, અમે ડેટાનું સંકલન કરીશું અને સંબંધિત તકનીકોની અસરનું આંકડાકીય વિશ્લેષણ કરીશું. તે તમારી સારવારને કોઈપણ રીતે અસર કરશે નહીં.

11.) શું ભાગ લેનાર દર્દીને ગુપ્ત રાખવામાં આવશે?

હા, તમારી માહિતી ગુપ્ત રાખવામાં આવશે અને તે કોઈ તૃતીય પક્ષને જાહેર કરવામાં આવશે નહીં અને તમારી પરવાનગી વિના ક્યાંય પ્રકાશિત કરવામાં આવશે નહીં. તમારી ઓળખ કોઈપણ સમયે જાહેર કરવામાં આવશે નહીં.

12.) દવાની કિંમત વિશે શું?

આ અભ્યાસ માટે તમારે કોઈ વધારાનો ખર્ચ ઉઠાવવો પડશે નહીં અને સામાન્ય એનેસ્થેસિયાના ખર્ચ સિવાય કોઈ ચાર્જ તમારા પર રહેશે નહીં. અભ્યાસમાં ભાગ લેવા માટે તમને કોઈ નાણાકીય પ્રોત્સાહન મળશે નહીં.

13.) શું મને અભ્યાસ વિશે બીજું કંઈ જાણવાની જરૂર છે?

તમારે ખાતરી રાખવી જોઈએ કે અમે અભ્યાસમાં જે દવાઓ અને તકનીકોનો ઉપયોગ કરીશું તે સારી રીતે સ્થાપિત થયેલ છે અને તેમની સલામતી દસ્તાવેજીકૃત કરવામાં આવી છે અને તેની ઓછામાં ઓછી આડઅસરો છે.

14.) કોઈપણ પ્રશ્નના કિસ્સામાં કોને કૉલ કરવો?

જો તમને અભ્યાસ સંબંધિત કોઈ વધારાની માહિતીની જરૂર હોય, અથવા જો તમને કોઈ શંકા માટે કોઈ સ્પષ્ટતાની જરૂર હોય, તો તમે તપાસકર્તાને પ્રશ્નો પૂછવા માટે મુક્ત છો. તમારી માહિતી અને રેકોર્ડ માટે તમને આ સહભાગી માહિતી પત્રકની એક નકલ આપવામાં આવશે. જો તમને વધુ વિગતોની જરૂર હોય, તો તમે તપાસકર્તાને કૉલ કરી શકો છો.

ડૉ. મેષા શેતલકુમાર શાહ
ઈમેઈલ: meshashahh@gmail.com
મોબાઈલ નં: +91 6355084827

CONSENT FORM

(Parul University Institutional Ethics Committee for Human Research)

I ‘ _____‘ have been explained the research project and also my role in the same.

I have been explained that the information provided by me shall be kept confidential and will in no way influence my receiving services from the hospital. I also understand that I can withdraw from the study at any point of the interview.

I agree to participate in the above research project voluntarily.

Witness signature (Signature/Thumb impression)

Name: Date:

Place:

We give one copy of the information sheet to our client.

સંમતિ ફોર્મ

(પારુલ યુનિવર્સિટી ઇન્સ્ટિટ્યૂશનલ એથિક્સ કમિટી ફોર હ્યુમન રિસર્ચ)

આથી હું સહી કરનાર _____ સમત્તી આપુ છું કે ઉપરોક્ત સંશોધન અભ્યાસ માંમારે શું ભાગ ભજવવાનો છે એનિ મને બરોબર સમજણ આપેલછે.

મને સમજાવવામાં આવ્યું છે કે મારા દ્વારા પૂરી પાડવામાં આવેલી માહિતી ગુપ્ત રાખવામાં આવશે અને તે હોસ્પિટલ તરફથી મને મળતી સેવાઓને કોઈપણ રીતે પ્રભાવિત કરશે નહીં. હું એ પણ સમજું છું કે ઈન્ટરવ્યુ દરમિયાન હું કોઈપણ સમયે અભ્યાસ છોડી શકું છું.

હું ઉપરોક્ત સંશોધન પ્રોજેક્ટ માં સ્વેચ્છાએ ભાગ લેવા માટે સમત્તી આપુ છુ.

સાક્ષીની સહી: _____ **(સહી/અંગૂઠાની છાપ)**

નામ: _____ **તારીખ** : _____

સ્થળ: _____

અમે અમારા ક્લાયન્ટને માહિતી પત્રકની એક નકલ આપીએ છીએ.

Version-1.3

SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

For VOLUNTARY reporting of Adverse Drug Reactions by Healthcare Professionals

INDIAN PHARMACOPOEIA COMMISSION

(National Coordination Centre-Pharmacovigilance Programme of India)
Ministry of Health & Family Welfare, Government of India
Sector-23, Raj Nagar, Ghaziabad-201002

Report Type □ Initial □ Follow up

FOR AMC/NCC USE ONLY

AMC Report No. :

Reg. No. /IPD No. /OPD No./CR no. :

Worldwide Unique No. :

A. PATIENT INFORMATION

1. Patient Initials _____

2. Age at time of Event or Date of Birth _____

3. M □ F □ Other □

4. Weight_____Kgs

12. Relevant tests/ laboratory data with dates

B. SUSPECTED ADVERSE REACTION

5. Date of reaction started (dd/mm/yyyy)

6. Date of recovery (dd/mm/yyyy)

7. Describe reaction or problem

13. Relevant medical/ medication history (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/renal dysfunction etc.)

14. Seriousness of the reaction: No □ if Yes □ (please tick anyone)

□ Death (dd/mm/yyyy) □ Congenital anomaly
□ Life threatening □ Required intervention to Prevent permanent impairment/damage
□ Hospitalization/Prolonged
□ Disability □ Other (specify)

15. Outcomes

□ Recovered □ Recovering □ Not recovered
□ Fatal □ Recovered with sequelae □ Unknown

C. SUSPECTED MEDICATION(S)

S.No	8. Name (Brand/Generic)	Manufacturer (if known)	Batch No. / Lot No.	Exp. Date (if known)	Dose used	Route used	Frequency (OD, BD etc.)	Therapy dates		Indication	Causality Assessment
								Date started	Date stopped		
i											
ii											
iii											
Iv											

S.No as per C	9. Action Taken (please tick)						10. Reaction reappeared after reintroduction (please tick)			
	Drug withdrawn	Dose increased	Dose reduced	Dose not changed	Not applicable	Unknown	Yes	No	Effect unknown	Dose (if reintroduced)
i										
ii										
iii										
iv										

11. Concomitant medical product including self-medication and herbal remedies with therapy dates (Exclude those used to treat reaction)

S.No	Name (Brand/Generic)	Dose used	Route used	Frequency (OD, BD, etc.)	Therapy dates		Indication
					Date started	Date stopped	
i							
ii							
iii							

Additional Information:

D. REPORTER DETAILS

16. Name and Professional Address:_____

_____

Pin:_____E-mail_____

Tel. No. (with STD code)_____

Occupation:_____ Signature:_____

17. Date of this report (dd/mm/yyyy):

Confidentiality: The patient's identity is held in strict confidence and protected to the fullest extent. Programme staff is not expected to and will not disclose the reporter's identity in response to a request from the public. Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the reaction.

Study Tools/ Questionnaire Study tools

Interviews
Observations
Survey
Case study
Photographs
Direct Measurements
Secondary