

## **INFORMED CONSENT FORM**

### **Title of Study:**

Perioperative analgesic management using Conventional versus Regional Nerve Block in craniotomy surgeries in lower middle-income countries.

### **Principal Investigator:**

Dr Dileep Kumar, Associate Professor, Department of Anesthesiology, Aga Khan University Hospital.

### **Co-Investigator:**

Dr Aqsa Rasheed, Trainee, Department of Anesthesiology, Aga Khan University Hospital.

### **Institute:**

Department of Anesthesiology, Aga Khan University Hospital, Karachi.

### **Document Date:**

05-04-2024

### **Introduction and Background:**

I, Dr Aqsa Rasheed, trainee in Department of Anesthesiology, Aga Khan University Hospital, Karachi, am conducting the above titled research in which we will compare systemic opioids with the pre-incision bilateral scalp nerve block for the intraoperative noxious stimuli and postoperative pain management in patients undergoing for the craniotomy surgery. Since you meet our inclusion criteria, I would like to invite you to participate in this study.

### **Purpose of this Research Study:**

Pain following craniotomies is found to be moderate to severe in intensity in the first 24 hours following craniotomy. Inadequate intraoperative and postoperative pain control is known to cause serious short- and long-term sequelae. There is currently no generally accepted opinion regarding which analgesic method is the most suitable for the perioperative pain treatment of patients undergoing elective brain tumor surgeries. Opioids have been regarded as the mainstay in the management of moderate to severe pain after craniotomy, however they are associated with side effects such as nausea, vomiting and respiratory depression, along with risk of oversedation that may interfere with postoperative neurological examination. Scalp nerve block (SNB) during craniotomy continues to be used and studied to have a potential benefit for patients undergoing craniotomy surgeries. Application of SNB is done prior to surgical incision by infiltration of the nerves supplying the scalp with local anesthesia on each side to blunt the hemodynamic response to noxious stimuli, stabilizing the intraoperative hemodynamics, allowing the smooth and faster emergence with lowered the postoperative pain scores<sup>1</sup>, and amount of opioid consumption.

Thus the aim of our study is to compare the systemic opioids with the pre-incision bilateral scalp nerve block for the intraoperative noxious stimuli and postoperative pain management in patients undergoing for the craniotomy surgery.

### **Procedure:**

A total of 31 patients will be recruited in the study in each group. If you agree to be a part of this study, you will be a part of the study from the start of anesthesia till 24 hours postoperatively. You will be randomized with the help of computer-generated blocks into either of the following two groups:

- **Group M (Systemic Morphine):** Patients will receive IV Morphine 0.1mg per kg at induction of anesthesia.
- **Group S (Bilateral Scalp Nerve Block):** After induction of anesthesia, bilateral scalp nerve block will be performed.

**Possible Risks:**

There are some known side effects of the drugs being used in the block and systemic analgesia such as, low blood pressure, bradycardia, nausea/vomiting, drowsiness, local toxicity, block failure. Any immediate complication will be recorded, and the management of these complications will be handled by the primary anesthesia team as per their feasibility.

**Alternative Treatment:**

If you do not want to participate in this study the standard of care provided to you will remain the same.

**Financial Considerations:**

There is no financial compensation for your participation in this research. There are no financial implications for the study subjects.

**Confidentiality:**

The information provided by you will remain confidential. Nobody except the principal investigator and the team members will have access to it. Your name and identity will also not be disclosed at any time. However, the data may be seen by the Aga Khan university Ethical Review Committee and may be published in a journal and elsewhere without giving your name or disclosing your identity. Codes for identifying data will be given to entries on SPSS (statistical package for the social sciences) to protect confidentiality.

**Right of Refusal to Participate and Withdrawal:**

You are free to choose whether to participate in this study. There will be no penalty or loss of benefits to which you are otherwise entitled if you choose not to participate. You will be

provided with any significant new findings developed during this study that may relate to or influence your willingness to continue participation.

**Available Sources of Information:**

Any further questions you have about this study or about your rights will be answered by the CoInvestigator, Dr Aqsa Rasheed.

In case if you wish to know more about your legal rights or in case of any injury during the study you may contact the Ethical Review Committee at the Aga Khan University Karachi at 02134864880. If you wish to know the compiled results after the completion of the study, please mention your email address or phone number here:

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**Authorization:**

I have read and understand this consent form, and I volunteer to participate in this research study. I understand that I will receive a copy of this form. I voluntarily choose to participate, but I understand that my consent does not take away any legal rights in the case of negligence or other legal fault of anyone who is involved in this study.

Participant's name:

Participant's signature/thumb impression:

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Date:

Primary investigator's/Co-investigator's signature:

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Date:

Witness signature : \_\_\_\_\_

Date :