



TITLE:

Distraction techniques for post-operative pediatric patients in post anaesthesia care unit (PACU); a randomized control trial

ERC number: 2020-2172-14474

Dated: 06-10-2021

Informed Consent Form

Title of Study: Distraction techniques versus conventional pain management; a randomized control trial in post op paediatric patients in Post Anaesthesia Care Unit.

Principal Investigator: Dr. Shemila Abbasi, Assistant Professor, Department of Anaesthesiology, Aga Khan University, Karachi

COPIs:

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Introduction:

I am Dr. Shemila Abbasi consultant of the Department of Anesthesiology, Aga Khan University. I am conducting research on Distraction techniques versus conventional pain management; a randomized control trial in post op paediatric patients in Post Anaesthesia Care Unit. Since your child meet the inclusion criteria, I would like to invite your son/daughter to participate in this research study.

Background information: For many years it has been observed that during recovery of children after general anaesthesia different methods are used to treat their pain, either by medication or distraction. And we try to find whether child is in real pain or it is anxiety due to some other factors.

Purpose: The purpose of this research is to compare the distraction method with the medication treatment in pediatric postoperative pain management.

Procedure:

If you agree to allow your child to participate in this project, your child would be part of either distraction method with medicine or medication group of patients, selected randomly (A method based on chance alone by which study participants are assigned to either group). Both these methods of treatment are used in other parts of world and it is not associated with any risk. It minimizes the differences among groups by equally distributing people with particular characteristics among all the trial groups. We will responsible for pain relief of your child either your child is in distraction or medication group. We will need to record and document our observations made during the postoperative period in the recovery room. Discharge from recovery room will be the end point of our study. This information will be vital in improving upon our current anesthesia practices and ensure better patient outcomes for the future.

Right of refusal to participate and withdrawal:

You are free to allow your child to participate in the study or refuse to participate without any risk of loss of benefit. Your child will receive the same standard care and treatment which is considered best irrespective of your child's participation in the study. You may also withdraw your child any time from the study.

Confidentiality:

The information provided by parent will remain confidential. Nobody except principal investigator will have access to it. Your child name and identity will not be disclosed at any time. However, the data may be seen by the ethical review committee and may be used for presentation or in conference or publication in journals and elsewhere without giving your child's name & identity.

Available sources of information:

If you have any further questions you may contact Principal Investigator Dr. Shemila Abbasi, Department of Anesthesia at Aga Khan University on following phone number 24 hours' emergency contact # 021-4862896.

AUTHORISATION

I have read and understand this consent form, and will allow my child to participate in this study. I understand that I will receive a copy of this form. I voluntarily allowed my child to participate in this study, 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. I further understand that nothing in this consent form is intended to replace any applicable federal, provincial, or local laws.

Participant's Name (Printed or Typed):

Date:

Participant's Guardian Name & Signature or thumb impression:

Date:

Principal investigator's Name & Signature:

Date:

Name & Signature of Person Obtaining Consent:

Date:

Name & Signature of Witness:

Date:

Form # _____

Date: _____