**Informed Consent Form for Research Project:**

"Emergence Agitation in Pediatrics after Dexmedetomidine vs. Sevoflurane Anesthesia: a randomized controlled trial"

Clinicaltrials.gov # NCT06482125

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**Appendix 1. Research Explanation Sheet**

# EXPLANATION SHEET TO THE SUBJECT CANDIDATE

I, Corry Quando Yahya MD from the Department of Anesthesiology and Intensive Therapy, Pelita Harapan University and Siloam Hospital Lippo Village will conduct a study entitled Emergence Agitation in Pediatrics after Dexmedetomidine vs. Sevoflurane Anesthesia: a randomized controlled trial

I will provide information to you about this research and invite your sons and daughters to be part of this research. You can participate in this study by signing this form. If you agree to participate in this study, you can freely withdraw from this study at any time. If you refuse to participate or withdraw from this study, the decision will not affect your relationship with me and will not affect the services that apply at this hospital. If you don't understand each statement in this form, please feel free to ask me.

## Research Objectives

In this study, your son/daughter will be given an anesthetic agent called Dexmedetomidine through a vein. This drug aims to provide a sleeping effect to the child during the surgical procedure. Side effects of giving Dexmedetomidine as an anesthetic includes a decrease in blood pressure and a decrease in heart rate. If there are these side effects, your child will be given medication to increase blood pressure and heart rate.

In this study, the time to recover from anesthesia and side effects such as agitation (restlessness) and decreased oxygen levels in the blood after anesthesia will be noted and compared with the administration of inhaled anesthetic (Sevoflurane). Through this research, we hope that your child will recover from anesthesia in a calm and gentle manner, in order to reduce complications from restlessness and in doing so may accelerate the healing process after surgery.

## Participation in research

Overall, the study is expected to take place until the target number of subjects specified has been met (approximately 1 year study time frame). If you decide to participate in this study, your son or daughter will receive the drug Dexmedetomidine during his or her surgery.

## Reasons for choosing subject

Your son/daughter was selected according to the criteria of this study, namely pediatric patients aged 2-5 years with an assessment of ASA 1 and 2 physical status (mild illness), have a good tolerance for enteral (oral) fluid, do not have hormonal system abnormalities and will undergo cleft lip or cleft lip surgery under general anesthesia.

## Research Procedure

1. Identify research subjects to assess eligibility.
2. Once the patient's parent or guardian has been provided with an explanation of the research procedure and agreed to participate in the study, the patient's parent or guardian will be asked to sign the consent. Identity and pre-surgical data are recorded.
3. In the preoperative room, patients are assessed and they will be randomly assigned into 2 groups: group X1 who will receive anesthesia with intravenous Dexmedetomidine and group X2 who will receive anesthesia using inhalation Sevoflurane. Dexmedetomidine or Sevoflurane will be the anesthetic maintenance agent used during the surgical process until it is completed.
4. The patient fasts during the fasting protocol. The last solid meal is consumed up to 6 hours before surgery, breast milk up to 4 hours pre-operatively and 2 hours for clear fluid such as water.
5. Patient arrives in the preparation room of the operating theatre in accordance with their time of operation.
6. In the operating room, saturation monitors, electrocardiography and non-invasive blood pressure monitors are installed. Each subject blood pressure and pulse rate were recorded from the time of induction. Induction is carried out with anesthesia standards using Sevoflurane inhalation until the child is asleep and an intravenous line is secured. Maintenance of anesthesia is carried out using Sevoflurane or Dexmedetomidine according to the child's designated group. After surgery is completed, recovery time and the incidence of decreased blood oxygen levels or agitating events will be assessed into two groups.

**Risk**

Side effects and management of anesthesia are a decrease in blood pressure and a decrease in heart rate. Guidelines for such treatment are the administration of intravenous (IV) fluids and drugs to raise blood pressure and pulse. The drugs and IV fluids are always provided at every operation.

**Benefit**

This study will be the first study to evaluate the use of Dexmedetomidine as a maintenance anesthetic agent for children undergoing cleft lip and cleft lip surgery.

**Compensation**

There is no compensation or reward for participating in this study.

**Financing**

This research was fully funded by the researcher.

**Concealment**

All data collected in this study will be kept confidential. We will display the identity of each respondent in the form of initials and can only be accessed by the research team and the ethics committee for verification. Presentation of research results in scientific meetings/conferences and publications in scientific journals will not include the name of your child.

**Obligations of the research subject**
As a research subject, you are obliged to follow the rules or guidelines for research as written above. If something is not clear, you can ask further questions to the research team.

**Right to refuse and withdraw from the study**
You do not have to participate in this research if you do not want to. You must understand that even if you agree to participate, you have the right to withdraw from this research. If you refuse to participate or withdraw from this research, the decision will not affect your relationship with me and will not have an impact on the standard of service that applies to this hospital. I will give you an opportunity at the end of this explanation to be able to consider the decision to be made.

**Post-trial access**
None

**Additional Information**
You are given the opportunity to ask all the things that are not clear in relation to this research. If at any time you need further explanation, you can contact me, Corry Quando Yahya at my mobile number 081383190900.

**Appendix 2.** Research Participation Consent Sheet

# CONSENT SHEET FOR PARTICIPATION IN RESEARCH

All these explanations have been presented to me and all my questions have been answered by the research team. I understand that if I need an explanation, I can ask Corry Quando Yahya, MD.

| **Consent form** | |
|---|---|
| I have read all the explanations about this research. I have been given the opportunity to ask questions and all my questions have been answered clearly. I am willing to participate in this research study voluntarily. I confirm that participants have been given the opportunity to ask questions about this study, and that all questions have been answered correctly. I confirm that consent has been given voluntarily. | I confirm that the participants have been given the opportunity to ask questions about this study, and that all questions have been answered correctly. I confirm that consent has been given voluntarily. |
| Subject Name / Guardian | Researcher/ Consent Requester |
| Signature of Guardian<br><br>Date_____<br>Day/month /year | Signature of researcher/ Consent requester<br><br>Date_____<br>Day/month/year |

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HP: 081383190900
Email: corry.spa@gmail.com, corry.yahya@lecturer.uph.edu

# CONSENT SHEET

I give consent to my child, with the name (_____) who participated in the study: Emergence Agitation in Pediatrics after Dexmedetomidine vs. Sevoflurane Anesthesia: a randomized controlled trial.

I have read and understood the information contained in the information sheet and have been given the opportunity to discuss and ask about it. I agree to allow my child to receive treatment according to the research protocol. I understand that I can refuse to participate in research. I am aware that I can withdraw from this research at anytime I desire to do so. I understand that if I do not participate in this study, my child will still receive medical care that is appropriate for his or her condition.

I, as the PARENT/GUARDIAN of : _____

AGREE to participate in this research.

Date:._____

Parent/Guardian Signature : _____

Parent/Guardian Name : ._____

Signature of Witness : _____

Name of Witness: _____

**Appendix 3. Consent Sheet for Publication**

# PUBLICATION AGREEMENT

I give my consent for the material about me/the patient to appear in a journal that my researcher will submit to.

I confirm that I: (please check to confirm)

- o have viewed photos, images, text or other material about me/the patient
- o have read an article to be submitted to a journal
- o I am legally entitled to give this consent.

I understand the following:

(1) The material will be published without my name/patient attached, however I understand that complete anonymity cannot be guaranteed. It is possible that someone somewhere – for example, someone who is caring for me/a patient or a relative – may recognize me/the patient.

(2) The material may show or include details of my / patient's medical condition or injury and the prognosis, treatment or surgery of any I/patient has, has or may have in the future.

(3) Articles will be published in journals distributed worldwide.

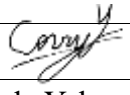
(4) Articles, including materials, may be the subject of press releases, and may be linked to/from social media. Once published, the article will be placed on the publisher's website and may also be available on third-party websites.

(5) I/the patient will not receive any financial benefits from the publication of the article.

(6) I can revoke my consent at any time before the author submits the article to the journal, but once the article is committed to peer review, it will not be possible to revoke consent.

| Signature (Parent or Guardian) | | | |
|---|---|---|---|
| Name | | Date | |
| Relationship to subject | | | |

Details of the person who has explained and provided the form to the patient or representative.

| Signature (Lead Researcher)  | | | |
|---|---|---|---|
| Name | Corry Quando Yahya | Date | |
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| Email | Corry.spa@gmail.com; corry.yahya@lecturer.uph.edu | | |