Cover Letter

Official Title: *Effectiveness and Safety of Nebulized Ketamine in Severe Pediatric Asthma: a Phase-2, Double-blind, Randomized, Placebo-controlled Pilot Trial*

NCT Number: Not yet assigned

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Parent/Guardian Information Sheet & Consent Form

Study Title: Effectiveness and Safety of Nebulized Ketamine in Severe Pediatric Asthma: a Phase-2, Double-blind, Randomized, Placebo-controlled Pilot Trial

Principal Investigator: Dr Zahraa Ali Hasan Al Lawati

Study Site: Sultan Qaboos University Hospital

Why is my child invited?

Your child is experiencing a severe asthma attack that requires hospital care. This is a **research study** to find out whether adding nebulized ketamine to standard treatment improves breathing more quickly and reduces the need for advanced respiratory support.

We plan to include about **60 children** in this study over the next **18–24 months**. We will collect information about your child's breathing and treatment from admission until discharge from the hospital.

What will happen in the study?

- Your child will be randomly assigned (like flipping a coin) to receive **either** nebulized ketamine **or** a placebo (normal saline), **in addition to** standard asthma treatment.
- The medication is given as **up to four nebulized doses** during the first **24 hours** of admission (every 6 hours, if still needed).
- Nurses/physicians will record breathing scores (PRAM), heart rate, respiratory rate, oxygen level, and blood pressure at regular intervals.
- **No extra blood tests or X-rays** are required for this study.
- Participation will **not delay, replace, or reduce** any medically necessary care. Your child will continue to receive all standard treatments for severe asthma that the doctors consider necessary, whether or not you join the study.

Risks & discomforts

Nebulized ketamine is generally well-tolerated. Possible mild side-effects include:

- dizziness or light-headedness
- mild agitation or feeling "strange"
- a bad or unusual taste in the mouth

Serious side-effects are **very rare**. All standard monitoring for severe asthma will be in place to detect and manage any problems promptly.

If your child has any medical problem that is thought to be related to the study of medicine, the doctors will treat it according to normal hospital policy, and you will not have to pay any extra costs for this care.

Benefits

Your child may or may not benefit directly. It is possible that ketamine will help breathing improve more quickly or reduce the need for stronger breathing support, but this cannot be guaranteed. The information gained could help improve future treatment for children with severe asthma attacks.

Voluntary participation & withdrawal

Taking part is **completely voluntary**.

- You may decide **not** to enroll your child; this will **not** affect your child's care in any way.
- You may withdraw your child from the study at **any time** without giving a reason. This will not affect the care or treatment your child receives.

The study doctor may also stop the study medicine if they believe it is in your child's best interest or for safety reasons, while continuing all other appropriate treatments.

Confidentiality

All information collected will be kept **confidential**.

- Your child will be identified only by a **study number** in the research records and database.
- Results will be published in a way that does **not** reveal any names or personal details.
- To check that the study is being carried out properly, **authorised persons** from Sultan Qaboos University Hospital, the Medical Research Ethics Committee, or health authorities may look at your child's medical record. They are required to keep all information confidential.

Costs & compensation

- There are **no costs** to you for taking part in this study.
- You will **not receive payment** for participation.
- Any research-related medical problem will be treated at Sultan Qaboos University Hospital according to usual hospital policy, without extra cost to you.

Questions or concerns

If you have questions at any time, please contact:

- **Principal Investigator:** Dr Zahraa Al Lawati – Tel: +968-92347374

If you have questions about your rights as a research participant or wish to make a complaint, you may contact the Medical Research Ethics Committee, College of Medicine & Health Sciences, Sultan Qaboos University (e.g. via the committee office/email as provided by the hospital).

Statement of Consent

I have read and understood the information above (or it has been read to me). I have had the opportunity to ask questions and they were answered to my satisfaction. I understand that my child's participation is voluntary and that I may withdraw my child at any time without affecting his/her medical care.

I **agree / do not agree** (circle one) for my child to participate in this study.

Child's Name: _____

Parent/Guardian Name: _____

Signature: _____ Date: _____

Witness Name (if required): _____

Signature: _____ Date: _____