INFORMED CONSENT STATEMENT

For children/minors participating in this study, the term
"*You*" addresses both the participant and the parents or legally authorized representative to consent.

PROJECT TITLE :
Ketamine for Acute Painful Crisis in Sickle Cell Disease Patients: Prospective Randomized Control trial
Name of the Principal Investigator:
Dr. Mohammed Alshahrani

1. You are being asked to participate in our study **Ketamine for Acute Painful Crisis in Sickle Cell Disease Patients: Prospective Randomized Control trial** for the period/duration of 24 months. You were particularly selected to participate in this study because this is a study that tests the benefit of using a medication that controls the pain that Sickle Cell Disease patients suffer during painful episodes. This usually involves long bones or spine but can involve other areas. Acute painful crises can also be triggered by cold exposure, dehydration (loss of body fluids, mostly water that exceeds the amount that is taken in), infection, hypoxia (your body does not have enough oxygen), acidosis (when your body fluids contain too much acid), or in some cases it is not related to a specific trigger. This condition puts the patient in severe pain requiring multiple ER visits and sometimes .admission to the hospital. Therefore many such patients receive a drug that suppresses pain
However, there is no evidence base treatment strategy that has proven effective in treating acute pain crisis in SCD. In addition, recent research suggests that despite the use of opioids and non-opioid drugs, .many SCD patients report inadequate pain control with high re-admission rate

In this study, we will enroll patients in the ED to ensure that patients or substitute decision makers are interested in participating, and to ensure that the study drugs are given as prescribed. This research project is important because the results of the study will have a big impact on the care of patients who visit the ER for SCD pain management in the future.
For research purpose, the procedures to be followed are: If you agree to participate and sign an informed consent, the research team will follow you while you are in the Emergency Room. You will receive either a low dose Ketamine or the standard opioid therapy. The study product that you will receive shall be determined by chance. That is, there is a 50% chance of receiving the Ketamine and a 50% chance of receiving the standard opioid treatment.

Patients allocated to receive the low dose Ketamine will receive 0.3mg/kg of Ketamine intravenously and will be repeated after 20-30 minutes. The first dose will be administered as soon as possible in addition to standard intra venous hydration.

Patients allocated to receive the standard opioid therapy will receive 1 mg of hydromorphone or equivalent dose of morphine and will be repeated after 20-30 minutes. The first dose will be administered as soon as possible in addition to standard intra venous hydration.

Your pain severity will be checked every 30 minutes until after 2 hours from the initial time the medication was given. If no pain relief was achieved after 2 doses of therapy, it will be up to your doctor to resume usual practice of managing painful crisis with morphine or you will be admitted to the hospital. All patients in this study will receive the usual nursing and medical care given by the ER team.
Your participation in the research study is voluntary. Before agreeing to be a part of this study please, read and/or listen to the following information carefully.
Feel free to ask questions if you have any ambiguities.

Ethics
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In addition, the investigator will acquire clinical data from your medical record at the hospital.

Any and all information obtained from your medical records during the study will be confidential. Your privacy will be protected at all times. You will not be identified individually in any way as a result of your participation in this research. The data collected however, may be used as part of publications and papers related to " Ketamine for Acute Painful Crisis in Sickle Cell Disease Patients: Prospective Randomized Control trial"

- "In case of any unexpected injury or illness during this study, the compensation or the necessary medical treatment will be given as per the rules and regulations of the hospital"
- Your participation in this study is entirely voluntary. You have rights to discontinue or refuse to participate even after initiation of study at any time for any reason. Such refusal will not have any negative consequences for you.
- Please feel free to talk to the researcher and ask questions. You may also want to talk to your family, friends, or your personal doctor or other health care provider about joining this study. If you decide that you would like to participate in the study, you will be asked to sign this form and you will be given a copy of the signed form to keep.
- After your participation, in case you have any questions and/or concerns about research, want clarification or report any matter related to your participation in the research you may contact **Dr. Mohammed Alshahrani** any time on the number 0556966663 or via email msshahrani@iau.edu.sa
- In addition, if any new information is learnt, at any time during the research, which might affect your participation in the study, you shall be informed.
- Principal Investigator of the study will also sign the copy of Informed consent and the signed copy of the Informed Consent will be handed over to the Study Participant. Also, Signed copy of informed consent has to be kept in the PI file, SCRELC file, and patient's medical record file.

I have read or listened to the above information and I have decided that I will participate in the project as described above. The researcher has explained me about the study, other beneficial treatments or procedures available and also clarified my doubts. I also understand what will be expected of me. If I do not participate, there will be no penalty or loss of rights. I can stop participating at any time, even after I have started.

I agree to participate in the study and for my samples to be kept and used for future research on pain management in SCD.

My signature below also indicates that I have received a copy of this English consent form.

Participant's signature ……..

Principal Investigator signature ……..

Witness - I ……..

Witness –II ……...

Ethics
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