Evaluation of Serum Copeptin and Psychological Stress Level Among Healthcare Providers During COVID-19 Pandemic

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(This template is for either clinical trials or clinical research)
(language used throughout form should be at the level of a local student of class 6th/8th)

Alexandria University Faculty of Medicine

Informed Consent form for is healthcare providers (doctors and nurses) both males and females who served in Alexandria quarantine hospitals in intensive care units, and who we are inviting to participate in research on Serum Copeptin correlates with Psychological Stress Level among healthcare providers during COVID-19 pandemic

Name of Principal Investigator: Hala Mourad Demerdash
Name of Organization: Alexandria University Faculty of Medicine Hospitals
Name of Sponsor: Alexandria University Faculty of Medicine
Name of Proposal and version: Serum Copeptin correlates with Psychological Stress Level among healthcare providers during COVID-19 pandemic
This Informed Consent Form has two parts:

- **Information Sheet (to share information about the research with you)**
- **Certificate of Consent (for signatures if you agree to take part)**

PART I: Information Sheet

Introduction

I am Hala Demerdash, working for the Alexandria University Faculty of Medicine, Hospitals. Investigators are doing research on serum copeptin level among healthcare providers both doctors and nurses serving in Alexandria quarantine hospitals in intensive care units and correlate it with psychological stress. The investigators are going to give participants information to be part of research. Before participants decide, they can talk to anyone of investigators staff they feel comfortable with about the research.

There may be some words that participants do not understand. They ask investigator to stop as they go through the information and investigator will take time to explain. If participants have questions later, they can ask them to the study staff.

Purpose of the research

Psychological stress is one of the most common problems among healthcare providers during COVID-19 pandemic, perceived psychological stress (PSS) influences the homeostatic equilibrium, involving activation of the sympathetic nervous system and hypothalamus pituitary adrenal (HPA) axis. Copeptin; C-terminal portion of Vasopressin (AVP) precursor is stable. Nevertheless, evidence about impact of PSS on copeptin levels is lacking. The reason investigators are doing this research is to find out level of psychological stress healthcare providers are exposed to during work in ICU intensive care unit during COVID-19 pandemic through a questionnaire coupled by measuring biochemical markers. Therefore, investigators evaluate these biomarkers before and after their work period in ICU.

Type of Research observational

This research is an observational research; in which it will involve a single blood sample withdrawn from participants arm as well as answering a questionnaire once again two weeks after leave.

Participant selection

investigators are inviting all healthcare providers' taking a period of two weeks shift in ICU at quarantine hospitals to participate in the research to evaluate level of psychological stress they confront, as well as serum copeptin.

- *Do you know why we are asking you to take part in this study?*
  ……..
- *Do you know what the study is about?*
  ……..
- *Do you know that you do not have to take part in this research study, if you do not wish to?*
  ……..
- *Do you have any questions?*
  ……..

Procedures and Protocol

The day before start of the two weeks' duty shifts in ICU; participants will take the questionnaire as well as fasting blood will be taken blood from their arm using a syringe and needle for serum copeptin and cortisol. Then second sample at end of first week and third sample two weeks after leaving quarantine. At the end of the research, any leftover blood sample will be destroyed.

B. Description of the Process

During the research you will take a questionnaire as well as three blood samples.

- In the first time, evaluation of condition clinically; determining BMI, blood pressure, then a small amount of blood, will be taken from your arm with a syringe. This blood will be tested for serum copeptin and cortisol (fasting morning sample). Investigator will ask participants a few questions about your general health and evaluate the level of stress (as anxiety, insomnia, fear of infection.)
- At the second time, one week after work in ICU, participants will again be asked some questions and another blood sample will be taken.
- The third time, two weeks after leave from ICU investigator will determine blood pressure, and BMI. Than a blood sample will be withdrawn. This will involve repeating the same laboratory tests.

Duration

four weeks for each participant. During that time, it will be necessary for participants will meet one of staff (research) three times, for few minutes each time.

Benefits

There may not be any benefit to the society at this stage of the research, but future is likely to benefit. As we would take into account the healthcare providers working in ICU confront some degree of stress that may be affect their general health and their performance.

- *Do you have any other questions?*
  ……..

Confidentiality

The information that Iinvestigator collect from this research project will be kept confidential. Information about you that will be collected during the research will be put away and no-one but the researchers will be able to see it. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will lock that information up with a lock and key. It will not be shared with or given to anyone except [name who will have access to the information, such as research sponsors].

- *Did you understand the procedures that we will be using to make sure that any information that we as researchers collect about you will remain confidential?*

- *Do you have any questions?*
  ……..

Sharing the Results

The knowledge that investigators get from doing this research will be shared with participants through community meetings before it is made widely available to the public. Confidential information will not be shared. There will be small meetings in the community and these will be announced. After these meetings, we will publish the results in order that other interested people may learn from our research.

Right to Refuse or Withdraw

participants do not have to take part in this research if they do not wish to do so. participants may also stop participating in the research at any time they choose. It is their choice and all of their rights will still be respected.

Who to Contact
State also that the proposal has been approved and how.

If you have any questions you may ask Ass Prof Dr Emad Arida, now or later, even after the study has started.
Name: Prof Dr Emad Arida
address: Anaesthesia and Surgical Intensive Care Department, Alexandria University Faculty of Medicine.
telephone number: 01223129135
e-mail: aridae@yahoo.com

This proposal has been reviewed and approved by Ethics Committee, Faculty of Medicine Alexandria University IRB No:00012098, which is a committee whose task it is to make sure that research participants are protected from harm.
If you wish to find about more about the IRB, contact address: Faculty of Medicine Alexandria University, 17 Champollion Street, El Messalah, Alexandria, Egypt.
telephone number: 01287740750.

- *Do you know that you do not have to take part in this study if you do not wish to?*
  ……
- *You can say No if you wish to?*
  ……
- *Do you know that you can ask me questions later, if you wish to?*
  ……
- *Do you know that I have given the contact details of the person who can give you more information about the study?*

……

PART II: Certificate of Consent
I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Print Name of Participant_____

Signature of Participant _____

Date _____
Day/month/year

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:

1. Serum blood samples will be withdrawn from participant arm one before start duty shifts start at ICU units in quarantine hospitals for determination of fasting copeptin, and cortisol in serum

2. Another serum blood sample will be one week after work in ICU and a third sample two weeks after leave taking from duty shifts for determination of same biomarkers in participant serum.

Investigators confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of study staff ability. Investigators confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.

Print Name of Researcher/person taking the consent: Dr. Hala Demerdash

Signature of Researcher /person taking the consent *Hala Demerdash*

Date: 15/2/2021.