Ain Shams University

Faculty of Medicine

Ethical Committee of Scientific research

Informed consent form for parents or guardians of patients who are invited to participate in the research

Research title: The incidence, risk factors and outcomes of electrolytes disturbances in critically ill Egyptian Patients: A single-Centre Prospective Cohort Study

Introduction and aim of the work:

Electrolytes imbalance (EI) is common in hospitalized patients as well as in the general population and is associated with increased morbidity and mortality. Clinically important EIs include dysnatremia, dyskalemia, dyscalcemia, dysmagnesemia, and dysphosphatemia. Electrolyte disorders are defined as an altered level of the following at least one of the electrolytes (potassium, chloride, sodium, or calcium level), that is, either increasing or decreasing from the normal range. The following ranges are used to determine the imbalance for each electrolyte: Na+= 135-145 mmol/L, K+= 3.5-5.5 mmol/L, Ca2+ = 2.1-2.55 mmol/L, and Cl− = 98-108 mmol/L, Mg+2 = 1.6-2.5 mg/dl, PO4- = 1.12-1.45 mg/dl. EIs have previously been investigated in several different cohorts. However, most previous studies have investigated one or two specific electrolytes in a selected group of patients with a single disease (e.g., heart or kidney disease), or in patients in a particular risk group (e.g., intensive care patients or patients using diuretics). In recent years, however, it has become clear that chronic and mild electrolyte disorders also are associated with adverse outcomes, including in the general population. Because of these emerging insights, it is important to know the exact prevalence and risk factors of electrolyte disorders in the general population. Mild electrolyte disorders are common in the general population aged 55 years or more (15%). Risk factors for electrolyte disorders in the general population are similar to those in hospitalized patients, including diabetes mellitus and all types of diuretics.

The aim of this study is to determine the incidence and risk factors of common electrolyte disorders in critically ill Egyptian people.

NCT06097104
Date of Document
26.9.2023

Place of work:

Anaesthesia, ICU and pain managment Department, Ain Shams University Hospitals.

Number and Selection of participants:

Will be 110 patients

Selection criteria for cases:

Inclusion Criteria:

All patients admitted to medical ICU, surgical ICU and CCU suffering from electrolyte imbalance (EI) over 18 years with the comorbid conditions like (hypertension, heart failure, chronic chest diseases, cancer, chronic kidney disease, diabetes mellitus, cardiac dysrhythmias, pneumonia, sepsis, dehydration, and critical bones fractures, etc.)

Exclusion criteria: **Patients with**

1. Age less than 18 year old
2. Patient or his 1st degree relatives refuse to participate
3. Patients without electrolytes data
4. Current smoking

Plan of the work:

After your consent achievement and fully explained about the steps of research, the subjects of groups will be subjected to the following:

1. ***Clinical parameters:***

Complete history taking and thorough clinical examination

2. ***Laboratory parameters:***

Lab.: "CBC – Kidney function tests – liver function tests – ABG – levels of serum sodium, potassium, magnesium, phosphorus, ionized calcium and chloride", with maximum 5 mm blood sampling per day. Serum-sodium levels will be corrected for serum-glucose by lowering the sodium concentration by 2.4 mmol/L for every 100 mg/dl increase in glucose.

Corrected Sodium = Measured sodium + 0.016 (Serum glucose - 100) A correction formula was also used to calculate albumin-corrected calcium levels (mmol/L)

Corrected Calcium = (0.8 (Normal Albumin - Pt's Albumin)) + Serum Ca

Benefits expected from the study:

The aim of this study is to determine the incidence and risk factors of common electrolyte disorders in critically ill Egyptian people.

Conducting the consent:

The consent will be conducted to the legal guardian or the patient by the investigator, Doctor Michael Mamdouh Anwar in the Anesthesia, ICU and pain management Department, Ain Shams University Hospitals. Literate individuals will be left to read the consent followed by its explanation by the mentioned investigator, while illiterate individuals will have the consent read and explained to them as well.

Risks and complications:

This research will not expose your patient to further risks or complications despite the standard risks of protocol of Ain Shams University hospitals.

The risk of blood sampling: The blood sample will be obtained by a trained, professional nurse using sterile, disposable equipment. The risks of bleeding, bruising, or infection are small, and similar to having blood drawn at your doctor's office. Some subjects report a feeling of faintness or brief dizziness upon blood sampling. However, the volume of blood (5 milliliters) is small, and will be replaced quickly by your body.

Reimbursements in cases of risks and complications:

Should your patient get physically injured as a result of research-related procedures, Doctor Michael Mamdouh Anwar will provide first-aid medical treatment.

Alternatives to participating:

In case of refusing to participate in this research, your patient will be followed up and will receive his treatment as planned.

Confidentiality:

You will deal in complete confidentiality, and no one has right to read your patient medical information except the main researcher. After the research is complete, you will be informed regarding your patient `s research results and also further information regarding your patient `s health status.

Right to refuse or withdraw:

Any participant doesn`t have to take part in this research if he/she or want. They may also stop participating at anytime. If you have read this form and have

decided to let your patient to participate in this study, please understand that your patient's participation is voluntary and you have the right to withdraw your consent or discontinue participation at any time without penalty or loss of benefits to which your patient is otherwise entitled. Your decision whether or not to participate in this study will not affect your patient's medical care. Individual privacy will be maintained in all published and written data resulting from the study.

Contact Information:

Questions, Concerns, or Complaints: If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the investigator, Michael Mamdouh Anwar at mobile number: 01273227589, You can also call the main supervisor Prof. Dr. Alaa Eid at mobile number: 01222167416

You do not have to sign this consent form. But if you do not, your patient will not be able to participate in this research study.

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 ask have been answered to my satisfaction. I consent voluntary to participate in this research and understand that I have the right to withdraw from the research at any time without in any way affecting my patient`s medical care.

- Name of participant:
- Signature of legal guardian:
- Or participant:
- Identity number or finger print: …….
- Date:

I have accurately read or witnessed the accurate reading of the consent to the potential participant. The individual has had the opportunity to ask questions I confirm that the individual has given consent freely.

- Name of researcher: Michael Mamdouh Anwar.
- Signature of researcher:
- Date:

This proposal has been reviewed and approved by Ethical Committee of Scientific research, which is a committee whose task is to make sure that research participants are protected from harm.

If you wish to find more about Ethical Committee of Scientific research. Contact:

Name:

Address:

Telephone number:

NCT06097104
Date of Document
26.9.2023