Impact of Zinc to Copper ratio and Lipocalin -2 in Obese Patients Undergoing Sleeve Gastrectomy.

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Informed Consent Form Template for Clinical Studies

(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 morbidly obese adults both men and women who attend bariatric surgery unit, and who we are inviting to participate in research on the Impact of Zinc to Copper ratio and Lipocalin -2 in Obese Patients Undergoing Sleeve Gastrectomy

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: Impact of Zinc to Copper ratio and Lipocalin -2 in Obese Patients Undergoing Sleeve Gastrectomy

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. We are doing research on micronutrient deficiency in morbid obesity as a disease, which is very common in this country "Egypt". I am going to give you information and invite you to be part of this research. You do not have to decide today whether or not you will participate in the research. Before you decide, you can talk to anyone you feel comfortable with about the research.

There may be some words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask them to me, the study doctor or the staff.

Purpose of the research

Morbid obesity is one of the most common and rapidly spreading in developing countries, this disease is associated with several comorbidities. Recent theories claim that morbid obesity may be associated with micronutrient deficiency which may play a major role in development of associated comorbidities. The reason we are doing this research is to find out if morbidly obese subjects suffer for micronutrient deficiency which may contribute to inflammatory response and development of comorbidities. Therefore, we evaluate micronutrient status before sleeve gastrectomy and after weight loss as determined by decreased BMI.

Type of Research observational

This research is an observational research; in which it will involve a single blood sample withdrawn from your arm as well as one follow-up visits to the clinic to determine BMI and take serum samples to evaluate micronutrients levels in subjects' serum once again after 9 months.

Participant selection

We are inviting all adult subjects with morbid obesity; BMI above 40 who attend obesity clinic for Bariatric surgery unit to participate in the research to evaluate micronutrient status in their serum.

you will still receive all the services they usually do whether they choose to participate or not.

- *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

During the initial visit after the complete clinical examination and before sleeve gastrectomy, determination of blood pressure, waist circumference and BMI. We will take blood from your arm using a syringe and needle for Complete blood picture, determination of biochemical parameters as fasting blood glucose, serum cholesterol, serum ferritin as well as lipocalin 2, serum copper and serum zinc. At end of research study period after 9 months, determination of blood pressure, BMI and waist circumference. Another blood sample will be taken from your arm for re-determination of same parameters. At the end of the research, any leftover blood sample will be destroyed.

B. Description of the Process

During the research you make three visits to the clinic.

- In the first visit, evaluation of condition clinically; determining if subject is eligible for sleeve gastrectomy, by measuring waist circumference, BMI, blood pressure, search for comorbidities as signs of anemia or nutritional deficiency. Then a small amount of blood, equal to about a teaspoon, will be taken from your arm with a syringe. This blood will be tested for micronutrient deficiency measuring biochemical parameters mainly zinc and copper. We will also ask you a few questions about your general health
- At the next visit, one month after operation, you will again be asked some questions about your health and you will be asked to report presence of complication as failure to lose weight.
- After 9 months, you will come back to the clinic to determine blood pressure, waist circumference and BMI. Than a blood sample will be withdrawn. This will involve repeating the same laboratory tests.

Duration

The research takes place over nine months in total. During that time, it will be necessary for you to come to the clinic/hospital/health facility 3 days, for few hours each day for follow-up. We would like to meet with you 9 months after your last clinic visit for a final check-up.

In total, you will be asked to come 3 times to the clinic in 9 months. At the end of 9 months, the research will be finished.

Benefits

If you participate in this research, 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 obese subjects be aware of micronutrients that may be deficient and may worsen the obesity disease.

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

Confidentiality

The information that we 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, your clinician.

- *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 we get from doing this research will be shared with you 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

You do not have to take part in this research if you do not wish to do so. You may also stop participating in the research at any time you choose. It is your choice and all of your 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 Ahmed Sabry, now or later, even after the study has started.
Name: Ass Prof Dr Ahmed Sabry
address: Bariatric Surgery Unit, Surgery Department, Alexandria University Faculty of Medicine.
telephone number: 01224263690
e-mail: ahmedsabry@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

If illiterate

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness_____ **AND** **Thumb print of participant**

Signature of witness _____

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 my arm one preoperative for determination of micronutrients in my serum
2. Another serum blood sample will be withdrawn 9 months postoperative for determination of micronutrients in my serum

I 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 my ability. I 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: 12/9/2020.