### 1. Title of research

Protein supplementation impact on body muscle mass and fat mass in Qataris post bariatric surgery, Randomized Controlled Trials (RCTs)

### 2. Principal Investigator

Sahar Al Shammari, Hamad Medical Corporation

### 3. Why are we inviting you to join this research?

We are inviting you to join because you are Qatari patient with age between 18-45 years who has undergone a bariatric surgery recently at HMC.

### 4. What should you know about this research?

- We will explain the research to you
- Whether or not you join is your decision (you can accept or refuse no matter who is inviting you to participate)
- Please feel free to ask questions or mention concerns before deciding, or during or after the research
- You can say yes but change your mind later
- We will not hold your decision against you

### 5. Who can you talk to?

If you have questions or concerns, or if you think the research has hurt you, talk to the research team at: Ms. Sahar AL Shammari 70995505 - 44396792

If you have questions about your rights as a volunteer, or you want to talk to someone outside the research team, please contact:
- HMC Medical Research Centre at irb@hamad.qa

### 6. Why are we doing the research?

HMC-IRB,16433/16,16Feb17-15Feb18

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**Notes:**

- تطلق المكتلات البروتينية على الكتلة العضلية والدهنية لدى القطريين بعد جراحة علاج السمنة: دراسة بحثية منضبطة عنوانية
- نموذج الموافقة على الاشتراك ببحث علمي
- RESEARCH CONSENT FORM

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**Else:**

- لطرح أية استفسار أو مناقشة أي مخاوف، أو إذا كنت تعتقد أن البحث قد أضر/بضرك، فبالتواصل مع فريق البحث على: 44396792 – 70995505
- إذا كان لديك أسلحة حول حقوقك كمشارك بالبحث، أو كنت ترغب في التحدث مع شخص من خارج فريق البحث، يرجى الاتصال ب irb@hamad.qa
- مركز الأبحاث، مؤسسة حمد الطبية، إيميل: irb@hamad.qa
This study is to see the impact of the intervention in post bariatric patient in many sides like weight reduction and improvement of nutritional status in general. We would like to assess the effect of protein supplementation on changes in health parameters in Qatari patients post bariatric surgery. We will be assessing these changes by measuring few parameters like muscle and fat mass, body weight, proteins, Vit B12 and minerals like Magnesium and Zinc.

7. How long will the research take?

We think that you will be in the research for 3 months starting from the first day post-operative.

We expect the research to last for 6 months.

8. How many people will take part?

We plan to study 80 people (post bariatric patients) from HMC. They will be divided in 2 groups equally.

9. What happens if you take part?

If you agree to take part, you will be “randomized” into one of 2 study groups - One will be intervention group and one would be the control group. This trial will be a double-blinded study.

Randomization means that you are put into a group by chance. It is like flipping a coin. You will have a 50% chance of being placed in a specific group. Neither you nor the researchers choose which group you will be in.

As a part of the standard care for post bariatric patients, all patients will receive nutritional counseling by a bariatric dietitian in a routine round, aiming that they will know the post-surgery diet stages and to not develop any nutritional deficiencies.

If you are from Intervention group:
1. You will receive nutritional counseling by a bariatric dietitian in a routine round, aiming that they will know the post-surgery diet stages and to not develop any nutritional deficiencies.
2. Before discharge from the hospital, you will have a store request for supplement and will be advised by the dietitian regarding its use (one can per day, over 3-5 intervals).
3. Supplement contains (per 200 ml can) 20 g of protein, 250Kcal plus different micronutrient and macronutrient (Cubitan Protein, Nutricia, Netherlands).

4. When you collect your supplement package from the hospital store, they will provide you with instructions about the use the supplement to ensure protocol is followed.

If you are in the control group:
1. You will receive nutritional counseling by a bariatric dietitian in a routine round, aiming that they will know the post-surgery diet stages and to not develop any nutritional deficiencies.
2. Before discharge from the hospital, you will have a store request for supplement and will be advised by the dietitian regarding its use (one can per day over 3-5 intervals).
3. Following hospital discharge, you will receive supplement contains per can (200 ml), 0g protein, fat free, 100 kcal and enriched with electrolytes (preOp, Nutricia, Netherlands).
4. When you collect your supplement package from the hospital store, they will provide you with instructions about the use the supplement to ensure protocol is followed.

Measurements for both groups:
- Baseline measurement of body composition (fat mass and muscle mass), height and weight will be conducted on day one of the trial.
- Baseline blood test for total protein, albumin, Vit B12, Zink and Magnesium levels.
- All of the above measurements will be repeated at 1 and 3 month after surgery. Collection of blood samples at 1 & 3 months post the surgery is part of routine practice for post-bariatric surgery patients.

Study visits for both groups:
One and 3 months after surgery (1 day each visit)
   a) Post-surgery dietary advice, to sustain a hypo caloric and protein-rich diet.
   b) Anthropometric parameters for body composition (fat and muscle mass will be measured to assess healthy weight).
   c) Give blood sample after an overnight fasting. All blood markers will be measured and calculated in the central laboratory in HGH.
   d) Both groups will be asked about their supplement compliance to determine their eligibility to continue in study.
   e) All randomized patients will be analyzed by intention to treat (ITT) analysis.

إذا كنت في مجموعة المقارنة:
1) ستحصل على استشارات غذائية عن طريق أخصائي التغذية أثناء الجولة الروتينية و ذلك لإرشادهم للتغذية السليمة بعد العمليات وال込んで مضاعفات بسبب نقص التغذية.
2) ستستلم طلب موجه للمخزن لإستلام مكمل غذائي و بعض الإرشادات عن أخصائي التغذية عن كيفية استعماله (عبوة واحدة يوميا على 3-5 فترات).
3) و تحتوي العبوة الواحدة للمكلل (200 مل) على 20 جرام بروتين، خالي الدهون، 100 كيلو كالوري و بعض العناصر الغذائية الحيوية.
4) بعد إستلام المكملات من مخزن المستشفى، سقومون بتزويدك بعض المعلومات الإضافية لضمان الاستخدام حسب متطلبات الدراسة.

قياسات للمجموعتين:
- قياسات أولية لكلة الجسم (العضلات و الدهون), الوزن، الطول في اليوم الأول للدراسة.
- تحليل دي أم أول فيترونيس متوسط البروتينات، الزلانك، فيتامين ب12، سيم إعداد القياسات السابق ذكرها بعد شهر و 3 شهور عند نهاية المشاركة في الدراسة.

زيارات بحثية للمجموعتين:
بعد شهر من الجراحة:
   a) تحصیل عن التغذیة ما بعد العملية للمحافظة على نظام قليل السعرات و غني بالبروتينات.
   b) قیاسات مؤشرات كتلة الجسم عینة من الدم بعد صراع ليلة. سیتم عمل التحالیل في مختبرات مستشفی حمید.
   c) حمد سیتم تداول المشارکین في المجموعتين عن التزامهم بالکمکلات
   d) تحديد مواصلاتهم في البحث.
   e) جميع المرضى الذين تم توزیعهم شنوینا سیتم تحالیلهم بطريقة "العیج" الخاصة (ITT Analysis).
10. Could the research be bad for you?

The research does not pose any risk to the participants in the intervention and control group. The intervention doesn't have any side effect for any of the 2 groups.

You will not be included in the study if you have:
1) Any Renal or liver disease because that will affect protein or albumin level in body.
2) Past history of bariatric surgery
3) Baseline tests showing you are in need for protein supplements. In this case, you will be given the needed protein supplements per the standard care.
4) You are not willing to participate.

11. Could the research be good for you?

There are no benefits to you from joining this research. However, possible benefits to others include the importance of intervention to their health status and weight reduction. If the protein intervention proves to be beneficial, we will recommend this to the respective authorities for implementation.

12. What happens to information about you?

We will make efforts to secure information about you. This includes using a code to identify you in our records instead of using your name. We will not identify you personally in any reports or publications about this research.

We cannot guarantee complete secrecy, but we will limit access to information about you. Only people who have a need to review information will have access. These people might include:
- Members of the research team whose work is related to the research or to protecting your rights and safety
- Representatives of the Ministry of Public Health who make sure the study is done properly and that your rights and safety are protected
- Your doctors and nurses

13. What if you don't want to join?

What if you don't want to join?
### 14. What if you join but change your mind?

You can say no and we will not hold it against you.

You can stop participating at any time and we will not hold it against you.

You may inform the research team through the available contact information and we will exclude the data we collected about you from this study.

### 15. What else should you know?

The research is approved by the Medical Research Center – HMC.

The researcher might stop this study at any time or decide to stop your participation in this study even if you want to continue. This could happen for the following reasons:
- If you did not take at least 80% of their intervention product amount per day, or
- If you did not take the intervention product (supplement) for more than 3 days per week.
Volunteer

I voluntarily agree to join the research described in this form.

Printed Name of Volunteer

Signature of Volunteer Date

Person Obtaining Consent

I document that:

- I (or another member of the research team) have fully explained this research to the volunteer.
- I have personally evaluated the volunteer’s understanding of the research and obtained their voluntary agreement.

Printed Name of Person Obtaining Consent

Signature of Person Obtaining Consent Date

Witness (if applicable)

I document that the information in this form (and any other written information) was accurately explained to the volunteer, who appears to have understood and freely given Consent to join the research.

Printed Name of Witness

Signature of Witness Date