Government of South Australia
SA Health

THE UNIVERSITY of ADELAIDE

ROYAL ADELAIDE HOSPITAL

INFORMATION SHEET

PROTOCOL NAME: Effects of a guar and whey containing preload (Omniblend) on gastric emptying and blood pressure responses to oral glucose in healthy older subjects.

YOUR PARTICIPATION IS VOLUNTARY

You are invited to take part in a study conducted by Professor Karen Jones, Dr Liza Phillips, Dr Hung Pham, Ms Lian Huynh, Ms Seva Hatzinikolas, Dr Tongzhi Wu, Professor Chris Rayner and Professor Michael Horowitz. This is a research project and you do not have to be involved. If you do not wish to participate, your medical care will not be affected in any way. Also, you may withdraw from the project at any time after you have commenced.

WHAT IS THE PURPOSE OF THE TRIAL?

Postprandial hypotension (PPH) is defined as a larger than expected fall in blood pressure following a meal – the more exact definition is a fall in blood pressure of greater than 20mmHg for a period lasting longer than 30 minutes, following a meal. PPH may lead to fainting and is common in older people. We do not fully understand why PPH occurs, however, the rate of stomach emptying has been shown to be an important factor in regulating blood pressure after a meal in healthy older subjects. The faster the stomach empties, the greater the fall in blood pressure. This may be associated with altered blood flow in the vessels around the stomach (the superior mesenteric arteries), which can be measured by ultrasound. We have shown in other studies that if we can slow the rate of stomach emptying, or if the absorption of nutrients from the upper gut (small intestine) is delayed, the fall in blood pressure after a meal is reduced.

This study involves a nutritional supplement known as Omniblend. This is a combination of guar gum and whey protein.

Guar gum forms a gel after it is eaten, and is not absorbed. We have shown that guar can decrease the drop in blood pressure following a meal by slowing both stomach emptying as well as the rate of absorption of nutrients from the gut (particularly the upper gut or small intestine). Whey is a protein which is a bi-product of the cheese-making process. We have shown that consuming a low dose of whey before a meal also helps slow stomach emptying.

We have recently studied this Omniblend supplement in ~ 40 patients with type 2 diabetes over 12 –weeks and looked at the effect of this treatment on blood sugar and stomach emptying. This supplement did slow the rate of stomach emptying and reduced blood sugar levels in this group. Importantly, the nutritional supplement was well tolerated in this study.

In this study, we are interested in seeing whether a preload containing whey protein and guar (Omniblend) can reduce the fall in blood pressure after a sugary drink – and also whether the rate of stomach emptying is affected by this preload.

WHAT WILL YOU HAVE TO DO?

This study involves one screening visit and two test days. At an initial screening visit, prior to entering the study, you will be asked to fill out a consent form for the study and we will ask you about your medical history. Specifically, we will attempt to exclude any stomach disorders, as well as epilepsy, diabetes, heart disease and previous/present allergies. You will also need to inform us of any medication that you are currently taking and how much alcohol you consume. You will also have a fasting blood sample (10ml) collected for the assessment of blood count, liver and kidney function, iron studies as well as a test for diabetes. During this screening visit, we will also obtain an ECG and blood pressure test which involves taking blood pressure and ECG while resting, deep breathing and standing.

The study involves two test days, separated by at least 5 days, performed in the Clinical Trial Facility located on level 4 of the new Adelaide Health and Medical Sciences Building in the

West End Precinct of North Terrace, each of which will take approximately five hours, beginning at about 8.30 am on each day. For each test, you will be required to fast (14 hours for solids and 12 hours for liquids) from the evening before each study.

On the test days, you will be seated with your back against a special camera that will measure the rate at which your stomach empties a sugary drink that contains a small amount of radiation.

A needle will be inserted into your arm vein (which may be associated with some minor, temporary, discomfort) for measurement of blood glucose and insulin. A blood pressure cuff will be placed around your opposite arm for measurement of blood pressure and heart rate.

You will then be allowed to "rest" for approximately 15 min to stabilise your blood pressure. On one study day, you will be given a preload of whey protein and guar 15 minutes before ingesting a test drink containing 50 g glucose in 300ml water and a small amount of radiation which can be detected by camera. On the other study day, you will only consume the test drink after the stabilisation period.

Blood pressure, heart rate and gut blood flow will be measured on a regular basis. Gut blood flow will be measured using ultrasound. To do this, lubricating jelly will be applied to your stomach and an ultrasound probe will be placed on your stomach. The ultrasound procedure should not cause any discomfort – it involves only light pressure and is not associated with any radiation exposure. We will ask you to rate sensations such as hunger, fullness, abdominal discomfort using a standardised questionnaire at regular intervals.

At the end of each study day, you will be offered a light lunch. After the meal, we will measure your blood pressure to ensure this is stable before you will be allowed to leave the Clinical Research Facility.

Smoking will be prohibited for 12 hours prior to, and on each study day.

The amount of blood taken during the two tests and blood screen will be approximately 300 ml in total. For comparison, the amount taken in an Australian Red Cross blood donation is between 350ml to 470ml. You should refrain from blood donation for the period of 10 - 12 weeks both prior to and following the trial in line with the Australian Red Cross guidelines.

STUDY PROCEDURE RELATED RISKS

The placement of the catheter in a vein in your arm may be associated with some minor, and temporary discomfort; bruising, and in rare and extreme cases, infection may also occur due to the insertion of the needle. The positioning of the venous cannula is also associated with a rare chance of blood clots (thrombosis) in the vein.

Sitting still in front of gamma camera for 3 hours may cause you a discomfort. However, in our extensive experience with this technique, studies are generally well tolerated. You will be given the opportunity to take a short break (~5 min) to stretch your legs at the end of each one hour study acquisition.

This research study involves exposure to a very small amount of radiation – approximately 1 milliSievert (mSv) in total for the two studies. As part of everyday living, everyone is exposed to naturally occurring background radiation and receive a dose about 2 mSv each year. At this small dose, no harmful effects of radiation have been demonstrated as any effect is too small to measure. The risk is believed to be very low.

The Omniblend preload may be associated with transient side effects including diarrhoea and flatulence, however, this is unlikely with a single dose.

Women of child-bearing age are excluded from this study.

RESEARCH RELATED INJURY

As stated, there is a possibility that insertion of the catheters may result in slight bruising and in rare and extreme cases, infection. You should contact us if the bruising or infection persists or concerns you. In the unlikely event that you are injured as a result of participation in this

study, care will be provided through the public hospital system. This study is indemnified by SA Health and the University of Adelaide but you also have the right to seek compensation through the legal system.

During the course of your screening visit or study, we may identify a new medical issue e.g. abnormal blood results such as iron deficiency or diabetes. The medical doctors involved in this study will speak to you, and with your permission contact your GP to share these results and organise appropriate ongoing care and follow-up.

IS THERE ANYTHING TO GAIN FROM PARTICIPATING?

This study is designed to provide information about the effects of a guar and whey containing preload on stomach emptying and blood pressure and will not benefit you. We estimate you will spend approximately five hours in the hospital on each study day. Payment for your participation is by way of honorarium at the rate of $20 per hour.

CONFIDENTIALITY AND DATA SECURITY

Your participation in this study is strictly confidential and will not be disclosed to other medical or research staff unless you agree. Any information that is published will be done in a way to protect your identity. Data generated from this study will not be used for any other purpose other than for this study. Blood samples will be stored temporarily until the samples can be assayed and any leftover material discarded using appropriate methods for biological waste. Hard copies of medical history, blood pressure, heart rate, appetite scores and blood test results will be stored. All numerical data will be stored on CD/USB. All data will be de-identified, however, if required we will be able to re-identify the data. Data will be stored in a secure location for a period of 15 years. Data will only be accessed by members of the research team. In addition to the processes described above, data may otherwise be discoverable through processes of law or for assessing compliance with research procedures. You have a right to access the information collected and stored by researchers about you. You also have a right to request that any information with which you disagree be corrected. You have a right to ask that any stored specimens be destroyed but should be aware that data which has already been derived from those specimens may not be able to be destroyed.

NAMES AND CONTACT NUMBERS OF INVESTIGATORS

Should you have any questions or concerns before or after the study, please contact either: *Professor Karen Jones (ph: 8313 7821) or Ms Seva Hatzinikolas (ph: 8313 7804) or Dr Hung Pham (ph: 8313 7808).*

INDEPENDENT CONTACT

The study will be conducted according to the NHMRC National Statement of Ethical Conduct in Human Research. The study has been approved by the Human Research Ethics Committee of the Royal Adelaide Hospital. If you would like to speak to someone not involved in the study about your rights as a participant, or about the conduct of the study, you may also like to contact the Chairman, Research Ethics Committee, Royal Adelaide Hospital on **8222 6841**.

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CONSENT FORM

PROTOCOL NAME: Effects of a guar and whey containing preload (Omniblend) on the gastric emptying and blood pressure responses to oral glucose in healthy older subjects.

INVESTIGATORS: Professor Karen Jones, Dr Liza Phillips, Dr Hung Pham, Ms Lian Huynh, Ms Seva Hatzinikolas, Dr Tongzhi Wu, Professor Chris Rayner and Professor Michael Horowitz.

1. The nature, purpose and risk of the research project have been explained to me. I understand them and agree to take part.
2. I understand that I will not benefit from taking part in the trial.
3. I understand that, while information gained during the study may be published, I will not be identified and my personal results will remain confidential.
4. I understand that I can withdraw from the study at any stage and that this will not affect my medical care, now or in the future.
5. I understand the statement concerning payment to me for taking part in this study, which is contained in the Information Sheet.
6. I understand that I must not have donated blood in the last 3 months and I should not donate blood for 3 months following the study.
7. I have had the opportunity to discuss taking part in this investigation with a family member or friend.

Name of Participant: _____

Signed: _____

Dated: _____

I certify that I have explained the study to the patient/volunteer and consider that he/she understands what is involved.

Signed: _____ Date: _____