**Activation of the ileal brake by carbohydrates and plant extracts –**

**A pilot study in ileostomy patients to develop sample collection and analytical methods**

**PARTICIPANT INFORMATION SHEET**

The University of Auckland Human Nutrition Unit in collaboration with Plant & Food Research are looking for ileostomy patients who are otherwise healthy, to take part in a nutrition study investigating whether simple dietary carbohydrate (white bread) can be prevented from being absorbed in the upper small intestine and travel down to the ileum.You are invited to take part in this study and your participation is entirely voluntary (your choice). If you do agree to take part, you are free to withdraw from the study at any time, without having to give a reason. You may take as much time as you like to consider whether or not to take part. If you require an interpreter, this can be arranged.

**Who designed the study?**

This is a study designed by the research staff at the Human Nutrition Unit at the University of Auckland, Mt Eden, Auckland and the New Zealand Institute for Plant & Food Research, Mt Albert, Auckland. The study will take place at the University of Auckland Human Nutrition Unit. For details of the research facility please view our website: [www.humannutritionunit.auckland.ac.nz](http://www.humannutritionunit.auckland.ac.nz)

**Why study appetite regulation?**

There is a rapidly growing epidemic of weight gain and obesity worldwide, as well as nationally within New Zealand. The gastrointestinal (GI) tract and specifically the most distal part of the small intestine, the ileum, may play a role in appetite suppression. It is thought that if foods reach the ileum they may apply a brake to eating, which is known as the ‘ileal brake’.

Our research team has already shown that if nutrients can reach the ileum by using a feeding tube hunger is suppressed and the amount of food eaten over the next few hours decreased. . In order to get dietary carbohydrate down to the ileum it has to pass through the upper small intestine without being absorbed. *Lab* tests by our research team have identified several natural plant nutrients (eg. from grape seed and quercetin) that may be able to be successful absorption blockers. The best way to test whether they do actually work, is to take them at the same time as some dietary carbohydrate (eg. white bread) and look to see whether any of the carbohydrate does arrive at the ileum. An easy way to do that is to collect samples from an ileostomy bag for 3-4 hours after a light meal.

**What are the aims of the study?**

The aim of this pilot study is to test our new carbohydrate absorption blockers in a group of ileostomy patients in whom it is possible to sample the contents of the ileum directly; and determine whether carbohydrate from a light meal (eg. white bread) can escape absorption and arrive intact at the ileum

**What happens if I decide to take part?**

This study requires a single visit, to the Human Nutrition Unit firstly for a brief (~40 minute) screen visit to determine your eligibility and secondly, if you are eligible, to take part in a 6 hour study. If you are interested, there are several arms to the study which you can take part in, or you can just take part once. All of the study days take ~4 hours, and starts with breakfast at 9am.

Screen Information This visit involves coming to the Human Nutrition Unit to hear more about the study, give signed consent and fill in paperwork concerning your medical history. You do not have to answer all of the questions and you may stop the interview at any time. We will also gather your demographic and anthropometrical data (age, gender, ethnicity, height, weight, body mass index (BMI), waist and hip circumference). If you are eligible and would like to, you can start the study immediately that day.

Study Visit: The study involves you coming into the Human Nutrition Unit for breakfast, and staying until early afternoon. There are 7 treatment arms, and in this pilot study you may take part in as many or as few as you choose. The study arm that you participate in will be allocated randomly (by chance):

1. Carbohydrate (CHO) breakfast only; no CHO blockers-
2. CHO breakfast + pharmaceutical CHO blocker (Acarbose)
3. CHO breakfast + grape seed, low dose
4. CHO breakfast + grape seed, high dose
5. CHO breakfast + quercetin, low dose
6. CHO breakfast + quercetin, high dose
7. CHO breakfast + grape seed plus quercetin

Each study day is identical, following the same schedule:

**0830h:** Arrive at the Human Nutrition Unit in the fasted state.

**0900h:** 2 MJ CHO breakfast immediately followed by the carbohydrate blockers, this will be given as a capsule to be swallowed with water.

**0900-1200h:** Ileostomy pouch contents sampled, to collect the nutrients that are delivered into the ileum. Collected at 0, 15, 30, 45, and 60 minutes, and then at 5 minute intervals for the following 2 hours.

We ask you to please not consume alcohol or undertake prolonged vigorous exercise on the day before test visits. During the day you are free to relax, read or watch Sky TV, DVD’s or any other sedentary activity. You are welcome to bring a laptop computer as wireless internet is available. You may not eat or drink any foods other than those provided by the study and you may not smoke. You may not leave the Human Nutrition Unit during the study.

**How many and what type of people will be in the study?**

We need seven ileostomy patients who have undergone prior large bowel resection but are otherwise healthy. Participants must be from the Auckland area, aged 20-65 years and BMI<40kg/m2.

**What tests will I have?**

We will collect contents from the ileostomy pouch throughout the study to measure how much dietary CHO escape absorption in the proximal small intestine and travel down to the ileum. There will always be experienced research staff present in the unlikely event you may need medical assistance. This is a dietary study, and hence all of the tests you will undertake are completely safe, but you may experience some abdominal discomfort potentially caused by the treatments. Thus, during the study we will also ask you to complete questionnaires throughout the day to assess if you experience any discomfort.

**The risk and benefits of the study**

Study staff will monitor you for any side effects and the study will be stopped should any harmful effects appear or if study investigators feel that it is not in your best interest to continue. Any symptoms that you may experience will be recorded as part of the trial and will be reviewed by an independent Medical Monitor.

Your weight, height, waist circumference, hip circumference and blood pressure will also be measured. None of these tests are dangerous. You are welcome to bring a friend or family member with you to your screen appointment to help you understand the study and any other explanation you may require.

Taking part in this study will require some of your time. The initial screen visit to determine your eligibility will take approximately 40 minutes. This visit can take place at any time that is convenient for you. The rest of the study involves coming in to the Human Nutrition Unit at 9.30 am before the study and staying at the unit until the end at around 12 pm.

**Compensation**

If you were injured in this study, which is unlikely, you would be eligible for compensation from ACC just as you would be if you were injured in an accident at work or at home. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery.

If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won’t affect your cover.

**Confidentiality**

Study files and all other information that you provide will remain strictly confidential. No material that could personally identify you will be used in any reports on this study. All data will be anonymised. Upon completion of the study your records will be stored in a secure place at the Human Nutrition Unit. All computer records will be password protected. Data will be kept for 10 years and will be the responsibility of the principal investigators*.* All future use of the information collected will be strictly controlled in accordance with the Privacy Act.

**Trial Payments**

There will be no financial cost to you for taking part in the trial. A gratuity and travel expenses will be paid to you at the screening visit and also at the end of your involvement in the study. The final amount will be made by direct debit into your bank account. You must have an IRD number to receive the gratuity payment, however you are welcome to participate irrespective. If for any reason you cannot stay for the entire study duration, you will be paid for the time you have contributed to the study.

**Finally**

If you would like some more information about the study please feel free to contact Hyun Sang Shin, PhD Student at the Human Nutrition Unit on telephone (09) 630 3744 or email to

h.shin@auckland.ac.nz.

If you want to talk to someone who isn’t involved with the study, you can contact an independent health and disability advocate on:

Phone: 0800 555 050
Fax: 0800 2 SUPPORT (0800 2787 7678)
Email: advocacy@hdc.org.nz

You can also contact the health and disability ethics committee (HDEC) that approved this study on:

 Phone: 0800 4 ETHICS

 Email: hdecs@moh.govt.nz

**The principal investigators of the study are:**

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 Scientist, New Zealand Institute for Plant and Food Research

 Mt Albert, Auckland

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***Please keep this information sheet for your records.***

 **Activation of the ileal brake by carbohydrates and plant extracts –**

# A pilot study in ileostomy patients to develop sample collection and analytical methods

Consent FormI have read and I understand the Patient Information Sheet dated xx xxxxxxx *2013* for volunteers taking part in the study entitled “Activation of the ileal brake by carbohydrates and plant extracts – A pilot study in ileostomy patients to develop sample collection and analytical methods” which is designed to assess the efficacy of (i) a starch breakdown inhibitor and (ii) a glucose uptake inhibitor, on the oral delivery of CHOs to the ileum, in a group of ileostomy patients in whom it is possible to sample the contents of the ileum directly.

I have had the opportunity to discuss this study with the investigator. I am satisfied with the answers I have been given.

1. I have had the opportunity to use support from a family (whanau) member or a friend to help me ask questions and understand the research.
2. I understand that taking part in this research is voluntary (my choice), and that I may withdraw from the research at any time and this will in no way affect my future or continuing health care.
3. I understand that my participation in this research is confidential and that no material which could identify me will be used in any reports on this research. I understand that the sponsor of the research, others working on the sponsor’s behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current research and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published.
4. I understand that the treatment, or investigation, will be stopped if it should appear harmful to myself.
5. I understand the compensation provisions for this research.
6. I have had time to consider whether to take part.
7. I know whom to contact if I have any side effects from the research.

8. I know whom to contact if I have any questions about the research.

|  |  |
| --- | --- |
| ***Participant to complete:*** *Please circle as appropriate* | Participant signature: |
| I consent to participate in the “Activation of the Ileal Brake – a pilot study in ileostomy patients”. | Yes | No |  |
| I wish to receive a copy of the results, when published. I understand that there may be a delay between data collection and the publication of the research results. | Yes | No |  |

***Participant to complete:***

I \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Print full name

of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Print address

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hereby consent to take part in “Activation of the Ileal Brake – a pilot study in ileostomy patients”

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature of participant

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date

***Researcher to complete:***

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Full name of researcher

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature of researcher

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Contact telephone number for researcher

***Researcher to complete:***

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Project explained by

 (On behalf of the Principal Investigator)

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Project role

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date

***A copy of this consent form is to be given to the participant and to be kept in their study file.***