Title of Research Study: A Low Biologically Available Glucose and High Protein Diet for Treatment of Type 2 Diabetes Mellitus (short title: The Diet and Diabetes Study)

Investigator Team Contact Information: Anne Bantle, MD

For questions about research appointments, the research study, research results, or other concerns, call the study team at:

Investigator Name: Anne Bantle, MD Investigator Departmental Affiliation: Department of Medicine	Study Staff: Lesia Lynse

If your doctor is also the person responsible for this research study, please note that she is interested in both your clinical care and the conduct of this research study. You have the right to discuss this study with another person who is not part of the research team before deciding whether to participate in the research.

Supported By: This research is supported by the National Institutes of Health/National Institute of Diabetes and Digestive and Kidney Diseases.

Key Information About This Research Study

The following is a short summary to help you decide whether or not to be a part of this research study. More detailed information is listed later on in this form.

What is research?

Doctors and investigators are committed to your care and safety. There are important differences between research and treatment plans:

- The goal of research is to learn new things in order to help groups of people in the future. Investigators learn things by following the same plan with a number of participants, so they do not usually make changes to the plan for individual research participants. You, as an individual, may or may not be helped by volunteering for a research study.
- The goal of clinical care is to help you get better or to improve your quality of life. Doctors can make changes to your clinical care plan as needed.

Research and clinical care are often combined. One purpose of this informed consent document is to provide you clear information about the specific research activities of this study.

Why am I being asked to take part in this research study?

We are asking you to take part in this research study because you have type 2 diabetes and are interested in trying a diet as a part of your treatment plan.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

The purpose of the study is to investigate the effects of two different diets as a part of a treatment plan for type 2 diabetes mellitus. These diets were designed to improve blood sugar control in people with type 2 diabetes. Participants in this study will be assigned to one of two diets. Both diets are acceptable according to current American Diabetes Association (ADA) recommendations.

How long will the research last?

We expect that you will be in this research study for 12 weeks.

What will I need to do to participate?

There will be six study visits at the University of Minnesota Clinical Research Unit. After the first visit you will be randomly assigned (like the flip of a coin) to one of two diets. You have an equal chance (50%) of being assigned to either diet. Instruction on how to follow the diet will be provided, and you will be asked to continue with your assigned diet for the next 12 weeks. You will need to purchase food and prepare meals based on the instructions we provide. Compensation for study participation will be provided, and is expected to help cover the cost of required foods. We will ask you not to change your

activity level and to stay about the same weight during the course of the study. We will also ask you not to make changes to your medications for diabetes during the study. A table is included at the end of this section to summarize study activities and visits.

More detailed information about the study procedures can be found under ***"What happens if I say yes, I want to be in this research?"***

Is there any way that being in this study could be bad for me?

The risks of study participation are as follows:

Overall risks of enrolling in study

There is a risk that your blood sugars will not improve during the course of the study. In this case, alternative recommendations for improving diabetes control will be provided at the end of the study. These recommendations would include advice to see your regular doctor to discuss a plan. The risk of a low blood sugar occurring during this study is very low.

The information gathered from this study will be saved as part of the research record. Although reasonable steps will be taken to ensure privacy, complete confidentiality cannot be guaranteed. Steps to protect the privacy of data will include storage in a locked area and password protection on all computers. You can decide not to answer any question at any time.

Risks associated with study diets

You will be asked to prepare and eat meals from your assigned study diet. You will be asked to avoid eating meals that are not a part of the diet and to avoid eating at restaurants while you are enrolled in the study. There is a risk that this may cause inconvenience to you. You will also be asked to purchase the foods necessary for your assigned diet. You will be given a stipend to partially cover the expected expense, but there is a risk that this stipend will not cover all of the additional food expense required by the study. In addition, there is a risk that you will not enjoy the meal plans provided for your assigned diet.

Risks associated with blood draws and IV placement

There is a risk for bruising, clotting, or infection at the site of blood draws or IV placement for blood draws. We will use standardized blood draw procedures to minimize these risks.

Risk associated with CGM device

There is a risk that minor skin irritation may occur at the CGM site.

Will being in this study help me in any way?

There is no guarantee that you will receive any benefits from taking part in this study.

What happens if I do not want to be in this research?

Whether or not you participate in this study, the usual care for your diabetes should continue. If you do participate in the study, we will ask you to continue the same diabetes medications without change and to stay the same weight during the course of the study. If you choose not to participate in the study, alternative approaches to improve blood sugar management might be offered by your doctor.

Detailed Information About This Research Study

The following is more detailed information about this study in addition to the information listed above.

How many people will be studied?

We expect about 50 people will be in this research study. This is the only site for this study.

What happens if I say "*Yes, I want to be in this research*"?

Screening

You will be asked questions about your health, diabetes history, current medications, weight, activity level, and diet.

Visit 1

We will go over this consent form with you. No procedures related to this study will take place until the consent form is signed. Next we will measure weight and height, and take blood and urine samples to determine your eligibility for the study. In total, 1-2 tablespoons of blood will be drawn at this visit. You will take a survey about your current diabetes treatment. We will provide instructions and supplies for collection of a stool sample at home. We may place a continuous glucose monitor (CGM) sensor that we will ask you to wear for two weeks. You will be blinded to data from this device. We expect this visit to last 1 hour.

Diet Recall Phone Call

You may be contacted by staff from the University of Minnesota for a 24 hour diet recall between Visit 1 and Visit 2. If this phone call occurs it is expected to take about 30 minutes.

Visit 2

You will need to fast overnight to prepare for the visit. You will be randomly assigned (like the flip of a coin) to one of two study diets. We will collect your stool sample and CGM sensor at this visit, or you can return these items by mail. We will ask you to complete a 3-day food diary to prepare for the visit. We will measure height, weight, and blood pressure, and take blood and urine samples for lab testing. We will place an IV in one arm to make blood sampling easier. You will be given a meal, and we will collect additional blood samples at regular intervals after the meal. In total, 2-3 tablespoons of blood will be drawn at this visit. You will consult with a study dietitian and will be given instructions for your assigned diet. We may give you an Actigraph Activity Monitor to wear until Visit 3. This device monitors your physical activity. We expect this visit to last 5 hours.

Visit 3

This visit will occur one week after Visit 2. At this visit we will measure weight and collect a urine sample. You will speak with the study dietitian to review your diet plan. We expect this visit to last 1 hour.

Every Other Week Phone Check-In

A study investigator will call you once every other week between Visit 3 and Visit 4, to provide encouragement and to answer any questions that may arise about your diet plan. This phone call is about 5-10 minutes.

Visit 4

This visit will occur when you are halfway through the 12 week diet intervention. You will be asked to bring in (or return by mail) a stool sample that you will collect at home and a 3-day food diary that you will be asked to complete to prepare for the visit. We will measure weight and blood pressure, and collect blood and urine samples for lab testing. In total, 1-2 tablespoons of blood will be drawn at this visit. You will speak with the study dietitian to review your diet plan. We will ask you to complete a survey. We expect this visit to last 1 hour.

Every Other Week Phone Check-In

A study investigator will call you once every other week between Visit 4 and Visit 5, to provide encouragement and to answer any questions that may arise about your diet plan. This phone call is about 5-10 minutes.

Diet Recall Phone Call

You may be contacted by staff from the University of Minnesota for a 24 hour diet recall between Visit 4 and Visit 6. If this phone call occurs it is expected to take about 30 minutes.

Visit 5

This visit will occur 3 weeks after visit 4. At this visit we will measure weight and collect a urine sample. You will speak with the study dietitian to review your diet plan. We will provide supplies for collection of a stool sample at home. We may place a CGM sensor that we will ask you to wear for two weeks. We may give you an Actigraph Activity Monitor to wear between Visit 5 and Visit 6. We expect this visit to last 1 hour.

Every Other Week Phone Check-In

A study investigator will call you once every other week between Visit 5 and Visit 6, to provide encouragement and to answer any questions that may arise about your diet plan. This phone call is about 5-10 minutes.

Visit 6 (Final Study Visit)

This visit will occur at the end of the 12 week diet intervention. You will need to fast overnight to prepare for the visit. We will collect your stool sample and CGM sensor at this visit, or you can return these items by mail. We will collect a 3-day food diary that you will be asked to complete to prepare for the visit. We will measure weight and blood pressure, and collect blood and urine samples for lab testing. We will place an IV in one arm to make blood sampling easier. You will be given a meal, and we will collect additional blood samples at regular intervals after the meal. In total, 2-3 tablespoons of blood will be drawn at this visit. We will ask you to complete a survey. You will speak with the study dietitian and, if you wish, receive recommendations for diet after the study is complete. We expect this visit to last 5 hours.

Schedule of Study Procedures

Visit	Screening	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Phone Call (every other week)	Diet Recall Phone Call (after Visits 1 and 5)
Estimated Length	20 min	1 hour	5 hours	1 hour	1 hour	1 hour	5 hours	5-10 min	30 min
Screening Survey	X								
Informed Consent		X							
Blood Draw		X	X		X		X		
Urine Sample		X		X	X	X	X		
Stool Sample			X		X		X		
Study Meal			X				X		
Meet with Dietitian			X	X	X	X	X		
Diet Survey		X			X		X		
3-Day Food Diary			X		X		X		
CGM Sensor (to be worn for 2 weeks)		X				X			
Actigraph Activity Monitor (to be worn between visits)			X			X			

What happens if I say "Yes", but I change my mind later?

Participation in this study is voluntary. Your decision on whether or not to participate in this study will not affect your current or future relationship with the University or the University of Minnesota Medical Center, Fairview. If you decide to participate, you are free to withdraw at any time without affecting those relationships.

Notification of Significant New Findings

You will be told of any important new information that is learned during the course of this research study, which might affect your condition or your willingness to continue participation in this study.

Will it cost me anything to participate in this research study?

There will be no cost to you or your insurance company for any of the procedures, laboratory testing, or visits required for the study. You will be asked to purchase the foods required for your assigned diet, and you will be provided with a stipend that will partially cover this cost.

Certificate of Confidentiality

To help protect your privacy, the National Institutes of Health has granted a Certificate of Confidentiality. The researchers can use this Certificate legally to refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate does not prevent a researcher from reporting information learned in research when required by other state or federal laws, such as mandatory reports to local health authorities for abuse or neglect of children/vulnerable adults, or information to the Food and Drug Administration (FDA) when required in an FDA audit. However, the Certificate limits the researcher from disclosing such information in follow up civil, criminal, legislative or administrative legal proceedings if the information was created or compiled for purposes of the research.

You also should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

The sponsor, monitors, auditors, the IRB, the University of Minnesota Research Compliance Office and other University compliance units, the US Office of Research Integrity (ORI), the US Office for the Protection of Human Research Protections (OHRP), the US Food and Drug Administration (FDA) may be granted direct access to your medical records to conduct and oversee the research. By signing this document you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

A description of this clinical trial will be available at http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete confidentiality. Organizations that may inspect and copy your information include the Institutional Review Board (IRB), the committee that provides ethical and regulatory oversight of research, and other representatives of this institution, including those that have responsibilities for monitoring or ensuring compliance (such as the Quality Assurance Program of the Human Research Protection Program (HRPP)).

Will anyone besides the study team be at my consent meeting?

You may be asked by the study team for your permission for an auditor to observe your consent meeting. Observing the consent meeting is one way that the University of Minnesota makes sure that your rights as a research participant are protected. The auditor is there to observe the consent meeting, which will be carried out by the people on the study team. The auditor will not document any personal (e.g. name, date of birth) or confidential information about you. The auditor will not observe your consent meeting without your permission ahead of time.

Whom do I contact if I have questions, concerns or feedback about my experience?

This research has been reviewed and approved by an IRB within the Human Research Protections Program (HRPP). To share feedback privately with the HRPP about your research experience, call the Research Participants' Advocate Line at 612-625-1650 (Toll Free: 1-888-224-8636) or go to z.umn.edu/participants. You are encouraged to contact the HRPP if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

Will I have a chance to provide feedback after the study is over?

The HRPP may ask you to complete a survey that asks about your experience as a research participant. You do not have to complete the survey if you do not want to. If you do choose to complete the survey, your responses will be anonymous.

If you are not asked to complete a survey, but you would like to share feedback, please contact the study team or the HRPP. See the "Investigator Contact Information" of this form for study team contact information and "Whom do I contact if I have questions, concerns or feedback about my experience?" of this form for HRPP contact information.

What happens if I am injured while participating in this research?

In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner, to you or your insurance company. If you think that you have suffered a research related injury let the study physicians know right away.

Will I be compensated for my participation?

The total stipend plus compensation for participating in this study will be $600 (paid as follows: visit 1 $30, visit 2 $75, visit 3 $40, phone call 1 $20, visit 4 $40, phone call 2 $20, visit 5 $40, phone call 3 $20, visit 6 $75, and a $240 bonus for study completion). If you need to withdraw from the study early, you will be compensated for the portion of the study which you were able to complete.

Payment will be made using a pre-paid debit card called Greenphire ClinCard. It works like a bank debit card. We will give you a debit card and each time you receive a payment for participation in this study, the money will be added to the card after each completed visit.

You may use this card at any store that accepts MasterCard or you can use a bank machine to remove cash. However, there may be fees drawn against the balance of the card for cash withdrawals (ATM use) and inactivity (no use for 3 months). We will give you the ClinCard Frequently Asked Questions information sheet that answers common questions about the debit card. You will also receive letters with additional information on how you can use this card and who to call if you have any questions. Be sure to read these letters, including the cardholder agreement, for details about fees.

The debit card system is administered by an outside company. The company, Greenphire, will be given your name and social security number. They will use this information only as part of the payment system. Your information will not be used for any other purposes and will not be given or sold to any other company. Greenphire will not receive any information about your health status or the study in which you are participating.

Payment you receive as compensation for participation in research is considered taxable income. If payment to an individual equals or exceeds $600 in any one calendar year, the University of Minnesota is required to report this information to the Internal Revenue Service (IRS). Research payments to study participants that equal or exceed $600 during any calendar year will result in a FORM 1099 (Miscellaneous Income) being issued to you and a copy sent to the IRS.

Use of Identifiable Health Information

We are committed to respect your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information that includes health information in your medical records and information that can identify you. For example, personal health information may include your name, address, phone number or social security number. Those persons who get your health information may not be required by Federal privacy laws (such as the 1099 Rule) to protect it. Some of those persons may be able to share your information with others without your separate permission. Please read the HIPAA Authorization form that we have provided and discussed.

How will my information be used in publications and presentations?

We may publish the results of this research in scientific, medical, academic or other journals or reports, or present the results at conferences. Information that makes it easy to identify you (such as your name and contact information, SSN and medical records number) will not be part of any publication or presentation. If you have an extremely unique or rare condition that is not shared by many others, it is possible that some people may be able to determine your identity even without these identifiers.

Optional Elements:

The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. Please indicate your willingness to participate in these optional activities by placing your initials next to each activity.

Yes, I agree	**No, I disagree**	
_____	_____	If you initial below to give us permission, we will store your blood, urine and stool samples for future testing. These samples will be stored using a unique code without personal identifiers. These samples will be stored indefinitely. Dr. Bantle will manage the use of these samples. Results from future testing of these samples will not be given to you. No genetic studies will be performed on these samples.
_____	_____	If you initial below to give us permission, we may contact you in the future about participating in other studies. Participation in any future study would be entirely voluntary.

Statement of Consent

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

_____ _____

Signature of Participant Date

_____

Printed Name of Participant

_____ _____

Signature of Person Obtaining Consent Date

_____

Printed Name of Person Obtaining Consent