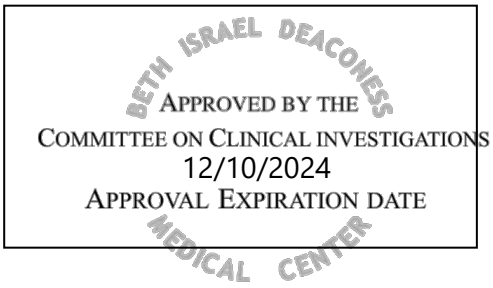
For CCI Use Only
Approved by the Beth Israel Deaconess Medical Center Committee on Clinical Investigations:

Consent Approval Date: 06/26/2024

Protocol Number: 2020P000622



INFORMED CONSENT FORM TO TAKE PART IN A RESEARCH STUDY

Subject's Name:
Title of Research Protocol: Effect of a low FODMAP diet on SIBO
Principal Investigator: Trisha Pasricha, MD, MPH
Protocol Number: 2020P000622

KEY INFORMATION

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

Why am I being invited to take part in a research study?
We invite you to take part in a research study because you experience chronic bloating that is not caused by an abnormality that can be found via bloodwork or endoscopy.

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.
- Your participation is completely voluntary.
- 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.
- Your refusal to participate will not result in any consequences or any loss of benefits that you are otherwise entitled to receive.
- You can ask all the questions you want before you decide.
- If you choose not to take part, or if you leave the study, your decision will in no way harm your relationship with any member of the research team or any other individuals at Beth Israel Deaconess Medical Center.

Why is this research being done?

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This study is being done to test the effects of a low FODMAP diet on chronic bloating. A low FODMAP diet is a diet that removes certain fermentable carbohydrates that are poorly absorbed by the body.

How long will the research last and what will I need to do?
We expect that you will be in this research study for five weeks.

You will be asked to have blood drawn, provide two stool samples, complete symptom questionnaires for the duration of the study, have two SIBO breath tests, and only eat or drink the low FODMAP foods that are provided to you for three weeks. A SIBO test measures abnormally high levels of bacteria in the small intestine by consuming glucose and then capturing breath samples for 90 minutes.

More detailed information about the study procedures can be found under ***"*DESCRIPTION OF STUDY DETAILS*".***

Is there any way being in this study could be harmful to me?
Risks of this study include your typical blood drawing tests and risk of loss of confidentiality.

More detailed information about the risks can be found under ***"*RISKS AND DISCOMFORTS*".***

Will being in this study help me in any way?
We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include reduction in symptoms of chronic bloating.

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

Participation in research is completely voluntary. You can decide to participate or not to participate.

Your alternative to participating in this research study is to not participate.

DETAILED INFORMATION SECTION

Please read this consent form carefully and ask the investigators or study staff to explain any words or information that you do not clearly understand. Once you read this consent form and understand what your participation in this study will involve, you will be asked to sign this form if you wish to take part. You will be given a signed copy of the form to keep for your records.

DISCLOSURE OF SPECIAL INTERESTS OF BIDMC AND INVESTIGATORS

This study is being conducted by Dr. Trisha Pasricha. There is no funding agency in this study. Neither Beth Israel Deaconess Medical Center (BIDMC) nor Dr. Pasricha have any additional interests in this research project.

WHOM TO CONTACT IF YOU HAVE QUESTIONS OR PROBLEMS

If you have any questions, concerns or complaints about this research or experience any problems, you should contact Dr. Trisha Pasricha at [617] 667-0161.

PURPOSE

Bloating is the most common symptom associated with disorders such as irritable bowel syndrome (IBS), a

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disorder characterized by abdominal (belly) pain and altered bowel habits which affects up to 11% of world population. A common cause of bloating is small intestinal bacterial overgrowth (SIBO), a condition defined by excessive and/or abnormal type of bacteria in the small bowel. Dietary factors are known triggers of IBS related symptoms.

Recent studies have suggested a low FODMAP diet may be beneficial in improving IBS symptoms, such as bloating. The purpose of this study is to study whether 3 weeks of a low FODMAP diet can reduce symptoms of bloating.

STUDY PARTICIPANTS

You have been asked to be in the study because you have chronic bloating that caused by SIBO (high bacteria levels in your small intestine).

Approximately 30 people will take part in this study at Beth Israel Deaconess Medical Center.

DESCRIPTION OF STUDY DETAILS

The study will consist of a 1-week baseline phase and a 3-week diet treatment phase.

If you agree to be in this study, you will be in this research study for about 5 weeks and you will be on the low FODMAP diet for 3 weeks.

After you sign the consent form, the following things will happen:

Screening Procedures: Screening procedures are tests and procedures that will be done to determine if you are eligible to take part in the research study. For this research study, the screening procedures include:

Visit 1 (This visit will last approximately two hours)

- We will obtain your medical history including what you have used to treat your symptoms.
- We will draw about 2 tablespoons of blood to test for markers of intestinal permeability. While pregnant women are not eligible for participation, we are not performing a pregnancy test.
- We will give you two stool collection kits to collect a stool sample prior to beginning the diet and after 3 weeks of being on the diet.
- We will perform a SIBO breath test. This test involves drinking a standard glucose solution followed by collecting your breath samples every 30 minutes for 90 minutes.
- For the duration of the study, you will complete questionnaires every day about your diet and gastrointestinal (GI) symptoms including abdominal discomfort, stool consistency and frequency. The questionnaires are done online via a secure website called REDCap. You do not need access to WiFi, but you do need access to the Internet. If you do not have access to the Internet, you will not be eligible to participate in the study. The questionnaires will take no more than 10 minutes to complete
- If you qualify for the study based on your GI symptoms, you will begin the low FODMAP diet in approximately one week.

Research Procedures: If you qualify to take part in this research study, you will undergo these research procedures:

Visit 2 (This visit will take place around a week after Visit 1)

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- You will return the first stool collection.
- You will continue to complete daily questionnaires of your GI symptoms and use of medication.
- You will begin the low FODMAP diet. You are required to not eat any foods or beverages (excluding water) except what is provided to you for the duration of the 3-week low FODMAP diet. The meals will be delivered to your home via UPS by Epicured. Epicured is a low FODMAP meal delivery service. You will be required to provide your name, contact information and full address to the study team who will give it to Epicured in order to participate in the study. Your information will be subject to Epicured's privacy policy which can be found at "epicured.com/privacy"
    - Epicured will deliver food approximately 2x/week to your house. They will provide meals that will need to be refrigerated or frozen. You will need to have sufficient refrigerator/freezer storage for at least 2 days worth of meals.
    - The meals will be either omnivore, pescatarian, vegetarian, or vegan. You will not have any choice in the food that is part of the study.
    - The meals are fully prepared and can be heated if preferred.
    - Epicured is a for-profit company and we are paying epicured to prepare and ship the meals to you.

Visit 3 (This visit will occur about three weeks after Visit 2 and last approximately two hours)

- We will draw about 2 tablespoons of blood to test for markers of intestinal permeability.
- You will return the second stool collection.
- We will perform a SIBO breath test. This test involves drinking a standard glucose solution followed by collecting your breath samples every 30 minutes for 90 minutes

Individual Research Results

Your study doctor will disclose any clinically relevant research results to you including the results of your SIBO tests.

Information and Biological Samples

Your information and biological samples will be used by the researchers involved in this study to conduct the research. The consent form provides information on who will have access to identifiable information and identifiable biological samples during the study. We also want you to know that your information or biological samples may be stripped of any identifiers (for example your name, medical record number or date of birth) and used for future research studies or distributed to another researcher for future research studies without additional informed consent. BIDMC researchers or other third party researchers may use your information and samples in other scientific research, product testing or commercial development. It is unknown whether a product will ultimately be developed from the research described in this consent form or from any such work that may be performed by BIDMC or other third parties receiving your information or biological samples. In signing this consent form, you are acknowledging and voluntarily consenting to the possibility that your information and biological samples may be used for commercial purposes. BIDMC and other researchers may benefit if this happens. There are no plans to pay you if your samples and information are used for this purpose.

If your identifiers are removed, we will not be able to destroy or remove your information or biological samples from distributed information or samples. As part of this research program and as further explained in this form, samples of your tissue and/or information about your medical history may be provided to other researchers and/or outside collaborators.

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Storing of Identifiable Information and Samples for Future Use

At the completion of this research, we would like to store any remaining sample(s) and information collected from or about you for this research for possible future use. Your sample will be stored without identifiers, such as your name or medical record number. The remaining samples and information may be stored indefinitely and may be used for future research of diarrhea and bloating. The research staff will have a list to know which sample is linked to which medical history and this list will be kept confidential in a secure location. If the research investigator distributes your samples to other researchers or institutions, they will be labeled with a research code without identifiers so that you cannot be identified by the other researchers or institutions.

If you have questions about storing samples or information, or would like to request that samples or information be removed from storage, please let us know. It is not always possible to remove samples or information from storage or to retrieve samples or information that have/has already been sent to other investigators.

I agree to allow my samples and information to be stored and used for future research as described above: (please check and initial one to indicate your choice)

_____ YES _____NO

RISKS AND DISCOMFORTS

DIET-RELATED RISK

If you have any known significant food allergies, you are not eligible to participate in this research study. However, a possibility exists that you have an unknown food allergy that is discovered as part of eating a meal provided by the research study.

BLOOD DRAW RISK

The risks and discomforts of blood drawing from a vein include the possibility of pain or bruising at the site of the blood draw, occasional feeling of lightheadedness, and rarely, infection at the site of the blood draw.

RISKS ASSOCIATED WITH SURVEYS/QUESTIONNAIRES

Some of the questions we will ask as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions and you may take a break at any time during the study. You may stop your participation in the study at any time.

Loss of confidentiality

There is the potential for loss of confidentiality by participating in this study. Every effort will be made to protect the confidentiality of your identifiable information.

CONFIDENTIALITY

Information learned about you during this research program will be maintained confidentially by the research staff as described in this form.

Information learned from your participation in this study and from your medical record may be reviewed and

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photocopied by the Food and Drug Administration (FDA) and/or other federal and state regulatory agencies, accreditation agencies, the Committee on Clinical Investigations, the Human Subjects Protection Office and others involved in research administration of the Beth Israel Deaconess Medical Center. Information resulting from this study and from your medical record may be used for research purposes and may be published; however, you will not be identified by name in such publications.

MEDICAL RECORD
The information collected during this research may become part of your medical record, if the information is relevant to the care you receive at Beth Israel Deaconess Medical Center. Medical records are considered permanent records; therefore, information cannot be deleted from the record. Medical records are available to health care professionals at Beth Israel Deaconess Medical Center and may be reviewed by staff when carrying out their responsibilities, as well as by external parties such as health care insurers and others in certain circumstances. If you are not currently a patient at Beth Israel Deaconess Medical Center and do not have a medical record at Beth Israel Deaconess Medical Center, one may be created for you for your participation in this research. You may also be required to register as a patient of Beth Israel Deaconess Medical Center in order to participate in this research.

POSSIBLE BENEFITS
It is not possible to predict whether you will benefit directly from participation in this study. However, your participation may help others in the future as a result of knowledge gained from the research.

OTHER AVAILABLE OPTIONS
Taking part in this study is voluntary. Instead of being in this study, you can choose to not participate.

IF YOU DECIDE NOT TO TAKE PART IN THE STUDY
Participation in this study is voluntary. You have the right to decide not to take part in this study. If you choose to participate, you have the right to leave the study at any time. Your decision to not participate will not result in any penalties or loss of benefits to you. The investigators will tell you about new information that may affect your willingness to stay in this study.

If you decide not to participate in the study or decide to leave the study early, your decision will not affect your relationship with the research team or any other individual at Beth Israel Deaconess Medical Center.

INVESTIGATORS RIGHT TO STOP THE STUDY
The investigators have the right to end your participation in this study if they determine that you no longer qualify to take part, or if it would be dangerous for you to continue, or if you do not follow study procedures as directed by the investigators. Beth Israel Deaconess Medical Center or the funding source may stop the study at any time.

COSTS AND/OR PAYMENTS TO YOU

Costs Covered by Study
You will not be charged for any of the tests or procedures that are part of this research study. You will not be compensated for taking part in this research study.

Cost of Research Related Injury:
If you are injured as a direct result of your participation in this study you should contact the Investigator at the

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number provided under the section "Whom to Call if You Have Questions" in this form. You will be offered the necessary care to treat your injury. You or your insurance company will be billed for medical care and/or hospitalization related to this injury. You will be responsible for all co-payments and deductibles required under your insurance. BIDMC will consider reimbursement of injury related expenses not covered by your insurance on a case-by-case basis. At this time there is no plan to reimburse you for items such as lost wages or lost time from work. By signing this consent form you have not given up any legal rights.

AUTHORIZATION FOR USE AND DISCLOSURE OF YOUR PROTECTED HEALTH INFORMATION
As part of this study, we will be collecting, using and sharing with others information about you. Please review this section carefully as it contains information about the federal privacy rules and the use and disclosure of your information.

Description of Protected Health Information [PHI]
By signing this informed consent document, you are allowing the investigators and other authorized personnel to use and disclose health information about you. This may include information about you that already exists (for example: your medical records and other sources of health information, demographic information, the results of any laboratory tests as well as any new information generated as part of this study. This is your Protected Health Information.

People/Groups at BIDMC Who Will Share and Use Your Protected Health Information
Your Protected Health Information may be shared with and used by investigators working on this study, including the supporting research team (such as research assistants and coordinators, statisticians, data managers, laboratory personnel, and administrative assistants), and may also be shared with and used by other health care providers at BIDMC who have treated you in the past and have information relevant to the research, or who provide services to you in connection with the research. Your Protected Health Information may also be shared with the members and staff of the Committee on Clinical Investigations of Beth Israel Deaconess Medical Center, which is responsible for reviewing studies for the protection of the research subjects, so that it can carry out its oversight responsibilities with respect to the study.

People/Groups Outside of BIDMC To Whom Your Protected Health Information Will Be Disclosed (Shared) and Who May Use Your Protected Health Information
We will take care to maintain confidentiality and privacy about you and your Protected Health Information. We may share your Protected Health Information with the following groups so that they may carry out their duties related to this research study:

- Epicured, the meal delivery service providing the meals.
- Other research collaborators and supporting research team members taking part in this study
- Any external health care providers who provide services to you in connection with this research
- Laboratories not affiliated with BIDMC that are involved in conducting tests related to the research
- Statisticians and other data monitors not affiliated with BIDMC
- The members and staff of any other IRBs (beyond the BIDMC Committee on Clinical Investigations) that oversee the research
- Centralized data collectors
- Your health insurance company
- The Food and Drug Administration [FDA], the Department of Health and Human Services [DHHS], the National Institute of Health [NIH], the Office for Human Research Protections [OHRP], and other

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federal and state agencies that may have jurisdiction over the research
- Hospital and Clinical Research Accrediting Agencies

Those who receive your Protected Health Information during the course of the research may not be required by the federal privacy regulations to protect it, and they may make further disclosures to others and use your information without being subject to penalties under those laws.

Purpose: Why We Are Using and Sharing Your Protected Health Information
The reason for using and sharing your Protected Health Information is to conduct and oversee the current, secondary, and future research described in this Informed Consent Document. There are many other reasons beyond the research for which BIDMC may use or disclose your Protected Health Information. Not all of these reasons require your express written authorization. For example, we will use and share your Protected Health Information to ensure that the research meets legal, institutional and accreditation requirements and to conduct public health activities. The various ways in which BIDMC may use and disclose your protected health information without your authorization are explained in a document called the Notice of Privacy Practices. If you have not received a copy of BIDMC's Notice of Privacy Practices, please ask us for one and review it before signing this form. In addition to signing this document, you may also be asked to sign a BIDMC General Agreement form acknowledging that you have received the BIDMC Notice of Privacy Practices.

No Expiration Date – Right to Withdraw Authorization
Your authorization for the use and disclosure of your Protected Health Information in this Study shall never expire. However, you may withdraw your authorization for the use and disclosure of your Protected Health Information at any time provided you notify the Principal Investigator in writing. If you would like to take back your authorization so that your Protected Health Information can no longer be used in this study, please send a letter notifying the Principal Investigator of your withdrawal of your authorization to Dr. Trisha Pasricha at 330 Brookline Ave., Boston, MA 02215. Please be aware that the investigators in this study will not be required to destroy or retrieve any of your Protected Health Information that has already been used or disclosed before the Principal Investigator receives your letter, and they are permitted to continue to use and disclose your previously collected information as necessary to complete the research.

Refusal to Sign
Your clinical treatment may not be conditioned upon whether you sign the Authorization for Research. However, if you choose not to sign this informed consent document and authorization for the use and disclosure of your Protected Health Information, you will not be allowed to take part in the research study.

Right to Access and Copy your PHI
If you wish to review or copy your Protected Health Information as it is made part of your medical record, you may do so after the completion or termination of the study by sending a letter to the Principal Investigator requesting a copy of your Protected Health Information. You may not be allowed to inspect or copy your Protected Health Information until this study is completed or terminated.

ADDITIONAL CONTACT FOR QUESTIONS OR CONCERNS
You may contact the Human Subjects Protection Office at [617] 975-8500 in the event that you would like to obtain information or to offer input about the research study. This office is independent of the investigator or investigator's research staff and can also assist with questions relating to your rights as a participant in

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research, which may include questions, concerns or complaints about your participation in the study.

THE FOLLOWING PARAGRAPHS CONTAIN SOME STANDARD INFORMATION WHICH GENERALLY APPLIES TO INDIVIDUALS PARTICIPATING IN A RESEARCH STUDY.

CONSENT FORM FOR CLINICAL RESEARCH

I have read the previous page[s] of the consent form and the investigator has explained the details of the study. I understand that I am free to ask additional questions.

If I wish additional information regarding this research and my rights as a research subject, or if I believe I have been harmed by this study, I may contact the Human Subjects Protection Office (HSPO).

I am aware that this is a research project and that unforeseen side effects may occur.

I understand that the Beth Israel Deaconess Medical Center has no formal program for compensating patients for medical injuries arising from this research. Medical treatment will be provided for injuries at the usual charge to me or to my insurer unless payment is otherwise provided for in this consent form.

I understand that participation in this study is voluntary and I may refuse to participate or may discontinue participation at any time without penalty, loss of benefits, or prejudice to the quality of care which I will receive.

I acknowledge that no guarantees have been made to me regarding the results of the treatment involved in this study, and I consent to participate in the study and have been given a copy of this form.

_____ _____

Signature of Subject or Legally Authorized Representative (Parent if the subject is a minor) — Date

_____

Relationship of Legally Authorized Representative to Subject

The subject has been given the opportunity to read this consent form and to ask questions before signing, and has been given a copy.

_____

SIGNATURE OF INVESTIGATOR/Co-Investigator DATE

_____

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PRINT INVESTIGATOR'S/Co-Investigator's NAME

A signing co-investigator must be listed on the study's approved Research Staffing Form at the time of consent.

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THE FOLLOWING SECTIONS ARE NOT NEEDED FOR ALL STUDIES AND SHOULD BE UTILIZED AS INDICATED:

If the subject is able to speak and understand English but is not able to read or write

I was present during the entire oral presentation of the informed consent and witnessed the subject's agreement to participate in the study.

Signature of Witness: _____

Printed Name of Witness: _____

Date: _____

If the subject is able to understand English but is not physically able to read or write or see

I was present during the entire oral presentation of the informed consent and witnessed the subject's agreement to participate in the study.

Signature of Witness: _____

Printed Name of Witness: _____

Date: _____

If the subject is not English speaking and signed the translated Short Form in lieu of the English consent document.

As someone who understands both English and the language spoken by the subject, I interpreted, in the subject's language, the researcher's presentation of the English consent form. The subject was given the opportunity to ask questions.

Signature of Interpreter: _____

Printed name of Interpreter: _____

Date: _____