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Title of Study: Chronotherapy in Inflammatory Bowel Disease

Sponsor: Rush Gastroenterology Department



Subject Information Sheet and Consent Form

Introduction

You are being invited to take part in this research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the information in this form carefully, as it may contain words you do not understand. You may wish to discuss it with your doctor, family, and/or friends. If there is anything that you do not understand or you would like more information, please ask questions and the study doctor or study staff will try their best to answer them. Once the study has been explained and you have had all your questions answered to your satisfaction, you will be asked to sign this form if you wish to participate. Before anything is done for this study, you must sign this form. A copy of this signed form will be given to you.

You do not have to take part in this study. You are free to withdraw from this study at any time you choose without giving a reason. This will not affect any future care you will receive. No promises can be made about the outcome of this as far as your current condition, either positive or negative. People who take part in research are called “subjects” instead of “patients”.

Why are you being invited to participate in this study?

You are being asked to take part in this study because you have been identified as a patient at Rush who has Inflammatory Bowel Disease (IBD) and is currently taking either azathioprine or 6-mercaptopurine to manage your symptoms.

What is the purpose of this study?

The purpose of this study is to see if there are any differences in the efficacy of an IBD medication as well as disease outcomes when one takes their medication for IBD in the morning or in the evening. Each individual has an internal clock that causes their enzyme levels to change at different times during the day. We think that this may have an effect on the efficacy of the medications prescribed for treating IBD, and that there may be a benefit to taking the medication at a certain time of day.

How many study subjects are expected to take part in the study?

We hope to have a total of 128 subjects enrolled in this study. Participants in this study will be assigned to take the medication they are currently taking in either the morning or in the evening based on when they currently take their medication for 10 weeks +/- 3 days.

What will you be asked to do?

This study will run for 10 weeks +/- 3 days.

Part 1: After you have reviewed this informed consent and signed it, you will be given 6 questionnaires. These are the Inflammatory Bowel Disease Questionnaire (IBDQ), the Munich Chronotype Questionnaire (MCTQ), the Owl and Lark Questionnaire, the Harvey Bradshaw questionnaire, the RU SATED questionnaire, and a demographics survey. You will be asked to complete these at the time of your first appointment. In addition, a blood draw will be performed to look at certain metabolite levels and other biochemical and subclinical indications of disease.

If you currently take – either azathioprine or 6-mercaptopurine – in the morning or the in the evening you will be asked to take your medication during the opposite delivery time for 10 weeks +/- 3 days. If you take it in the morning, you will be asked to take it between 6am-12 pm. If you are assigned to take it in the evening, you will be asked to take it between 6pm-12 am.

Part 1a: During the 10 weeks +/- 3 days, as a part of your normal clinical care routine visits, if clinically-indicated imaging is necessary, then this data will be collected, too. No imaging will be performed outside of what is clinically-indicated.

Part 2: During the second appointment you will be given 2 questionnaires. These are the IBDQ and Harvey Bradshaw questionnaire. In addition, a blood draw will be performed to look at certain metabolite levels and other biochemical and subclinical indications of disease.

How long will you be in the study?

You can expect to be in this study for 10 weeks +/- 3 days.

You may be removed from this study without your consent. Possible reasons may be that the study doctor decides that continued participation in the study will be harmful to you, you will need a treatment not allowed on the study, your disease becomes worse, you are unable to take the treatment as directed, or the study is canceled.

What are the possible risks of the study?

We do not foresee any major risks or discomforts associated with this study, as we are not changing the medication or the dose of the medication you currently take. However, the side effects of taking your medication can still apply – with immunomodulators like azathioprine and 6-mercaptopurine – there is a risk of nausea, vomiting, diarrhea, rash, fever, weakness, or muscle pain. Additionally, you will have your blood drawn. There are minimal risks associated with blood draws. Drawing blood involves placing a tight wrap on your upper arm and inserting a needle into a vein in your arm and withdrawing blood. You may experience discomfort at the time of blood draw and/or bleeding, and bruising at the site where the needle enters the body. In rare cases, fainting or infection may occur. To minimize discomfort and local bruising, an experienced nurse or technician will complete the blood draw.

Are there any anticipated pregnancy risks?

Women

If you are pregnant or breastfeeding, you cannot take part in this study. You are responsible for

using an effective birth control method such as birth control pills, barrier method (such as condoms or diaphragms), intrauterine device (IUD), hormone implants or surgical sterility while you are taking part in this study. Once you have completed treatment, you may discontinue birth control. If you become pregnant, you must notify the study doctor immediately.

Men

You are responsible for using an effective birth control method, such as the ones listed above. If you are a male and your female partner becomes pregnant, you must notify your study doctor immediately. Once you have completed treatment, you may discontinue birth control.

Are there benefits to taking part in the study?

There may be no direct benefit to you for participating in this study. However, by participating in this study, we may find that there is an optimal time of day for patients to take their prescribed medication in order to best manage IBD symptoms and have a better quality of life. We hope to find that there is a time of day that optimizes the efficacy of the medication and minimizes its side effects.

What other options are there?

The only alternative to participating in this study is not to participate. You do not have to participate in this research project in order to receive care and treatment from Rush University Medical Center, and choosing not to participate will not affect your care.

What about confidentiality of your information?

Records of participation in this research study will be maintained and kept confidential as required by law. Each study participant is assigned a code, and his/her data will be entered anonymously into a chart. We will then link the questionnaire and endoscopic results to this data via participant codes. Permission controls and passwords will assure that only the key personnel listed in the IRB review application will be able to enter data into and access the database. All access into the database will be electronically monitored, complete with time and date of access, to ensure security and fidelity of the database material. The database will be stored electronically on a secure server in the PI's office in the Rush Professional Office Building Suite 206 and will be password protected. The database will be saved and maintained for approximately 5 years.

If you withdraw from this study, the data already collected from may not be removed from the study records. The study doctor and/or study team may ask you whether they can continue to collect follow-up data on you. If follow-up information will be requested, you will be asked to sign a separate consent form before this information can be collected. In the event that a subject revokes authorization to collect or use PHI, the investigator, by regulation, retains the ability to use all information collected prior to the revocation of subject authorization.

Your identity will not be revealed on any report, publication, or at scientific meetings.

In order to conduct the study, the study doctor, Dr. Swanson, will use and share personal health information about you. This includes information already in your medical record, as well as information created or collected during the study. Examples of the information that may be shared include your medical history, physical exam and laboratory test results. The study doctor will use this information about you to complete this research.

Confidentiality and disclosure of your personal information is further described in the attachment to this form. The attachment is titled HIPAA Authorization to Share Personal Health Information in Research (2 pages).

The Rush Institutional Review Board (IRB) will have access to your files as they pertain to this research study. The IRB is a special committee that reviews new and ongoing human research studies to check that the rules and regulations are followed regarding the protection of the rights and welfare of human subjects.

What are the costs of your participation in this study?

All costs that are part of your usual medical care, such as routine clinic visits and the continued use of your prescribed medication – azathioprine or 6-mercaptopurine – will be charged to you or your insurance company. You will be responsible for all costs that are not paid by your insurance company. You should check with your insurance company before you enroll in this research study.

Will you be compensated or paid?

You will not be compensated or paid from participating in this study.

What happens if you experience a research related injury?

If you experience any injury or illness as a direct result of your participation in this research study, immediate treatment will be provided. However, the cost of that treatment will be billed to you or your insurance company. Please check with your insurance company regarding coverage. If you have any medical problems during the study, please contact the study doctor. He or she will explain your treatment options to you and/or help you find a place to get treatment. Rush University Medical Center has no program for financial compensation or other forms of compensation for injuries which you may incur as a result of participation in this study.

What happens if you need emergency care?

If you need emergency care while you are participating in this study, it is important that you tell emergency personnel of your participation in this study and notify the study doctor as soon as possible.

Whom do you call if you have questions or problems?

Questions are encouraged. If there are any questions about this research study or if you experience a research related injury, please contact: Dr. Garth Swanson at (312-942-5861). Questions about the rights of research subjects may be addressed to the Rush Research & Clinical Trials Administration Office at 1-800-876-0772.

By signing below, you are consenting to participate in this research study. You have read the information given or someone has read it to you. You have had the opportunity to ask questions, which have been answered satisfactorily to you by the study staff. You do not waive any of your legal rights by signing this consent form.

SIGNATURE BY THE SUBJECT:

Name of Subject

Signature of Subject

Date of Signature

SIGNATURE BY THE INVESTIGATOR/INDIVIDUAL OBTAINING CONSENT:

I attest that all the elements of informed consent described in this consent document have been discussed fully in non-technical terms with the subject. I further attest that all questions asked by the subject were answered to the best of my knowledge.

Signature of Individual Obtaining Consent

Date of Signature

Check here if the Individual Obtaining Consent observed the signing of this consent document and can attest, to the best of their knowledge, the person signing the consent form is the subject or the subject's legally authorized representative and the person signing the form has done so voluntarily. By checking this box, the Individual Obtaining Consent does not need to sign on the Witness signature line (below).

SIGNATURE BY WITNESS/TRANSLATOR

(for use if this consent is being used as a written summary of the research along with a short form consent OR when the person obtaining consent is not the witness):

I observed the signing of this consent document and attest that, to the best of my knowledge, the person signing the consent form is the subject or the subject's legally authorized representative and the person signing the form has done so voluntarily.

Signature of Witness/Translator

Date of Signature

Check here if a separate witness signature is not necessary.

SIGNATURE OF THE PRINCIPAL INVESTIGATOR

I attest that I am aware of the enrollment of this subject in the study discussed in this consent document.

Signature of the Principal Investigator

Date of Signature

Check here if Principal Investigator obtained consent and a separate signature is not required.