CONSENT TO PARTICIPATE IN RESEARCH

The University of Mississippi Medical Center

Study Title: Identification of Surrogate Blood and/or Urine Biomarker for Immulina™ in Normal Humans

Principal Investigator: Gailen D. Marshall, Jr., MD, PhD

Key Information

This research study seeks to identify specific substances (called biomarkers) in the blood and in urine of volunteers that take a natural dietary supplement, Immulina™. If you participate, you will be given one dose (4 capsules) of Immulina™ and have blood and urine collected 4 times. Your participation will last one day, up to 7 hours total. You may experience potentially rare, but minor risks including nausea, vomiting, diarrhea, stomach pain, dry mouth, fever, chest pain or discomfort, back pain, drowsiness, headache or skin rash or itching. It is unknown if you will receive a direct benefit. If you have questions, call Dr. Gailen D. Marshall, Jr. at (601) 815-1078.

Introduction

You are being asked to join in a research study because you are aged 18-50, are generally healthy and may or may not have a disease controlled by medication. Please ask us about anything in this document or that you do not understand. It is your choice to participate in this study, and you can change your mind later.

Purpose

We are doing this study to identify specific substances (called biomarkers) in the blood and in urine of volunteers that take a natural dietary supplement, Immulina™.

Procedures

Assessment	Screening	Baseline, Enrollment, Time = 0	Time=1 hour post	Time=3 hours post	Time= 6 hours post
Informed Consent Form	X				
Confidentiality Agreement	X				
HIPAA Authorization	X				
Demographics	X				
Medical History	X	X			
Concomitant Medications	X	X			
Urine Collection	X	X*	X	X	X
Blood Collection		X	X	X	X
Urine Pregnancy Test (females of childbearing potential only)	X				
Inclusion/Exclusion Criteria	X	X			
Treatment Administration		X			
Adverse Events		X	X	X	X
Biomarker Assessments		X	X	X	X

*Urine will be collected at baseline on males and females that are not of childbearing potential.

If you decide to join this research study, a study team member will talk to you about your medical and medication history. After completing the initial screening and if you qualify for the study, the study team will schedule a screening visit at the study site. Your participation will involve 1 study visit, lasting up to 7 hours and will take place at the UMMC Clinical Research and Trials Unit. At the screening visit, you will arrive at the study center fasting for at least 2 hours prior to arrival and have avoided a "high fat" diet for 12 hours prior to arrival. You will undergo a review of the consent form with the study team. Please ask any questions you may have about the study.

After consenting to participate in the research study,

- If you are female and have childbearing potential, we will ask you to collect at least 3 ½ tablespoons of urine in a cup and we will perform a urine pregnancy test.
- The study team will review the study criteria to determine your qualification to continue to participate in the study.

Baseline:

- You will have a choice to either have a venous peripheral catheter (similar to an I.V. needle) inserted into your vein for the duration of the study visit or have 4 separate blood collections over the duration of the study visit. Using the catheter will allow us to collect repeated blood samples during the study visit and lower the risk of bruising,
- We will draw about 1 ½ tablespoons of blood.
- If you are a male or a female that does not have childbearing potential, we will ask you to collect at least 3 ½ tablespoons of urine in a cup.
- You will be given 4- 200 mg capsules of Immulina™, a natural dietary supplement, with a glass of water.
- We will encourage you to consume fluids (coffee, tea, soft drinks or juices) throughout the course of the study visit.

One hour post-Immulina ingestion:

- We will draw about 1 ½ tablespoons of blood and ask you to collect at least 3 ½ tablespoons of urine in a cup.

Three hours post-Immulina ingestion:

- We will draw about 1 ½ tablespoons of blood and ask you to collect at least 3 ½ tablespoons of urine in a cup.

6 hours post-Immulina ingestion:

- We will draw about 1 ½ tablespoons of blood and ask you to collect at least 3 ½ tablespoons of urine in a cup.
- The catheter in your arm vein will be removed and bandaged.

Length of Participation

Your participation will last up to 7 hours on one day only.

Number of Participants

We expect 20 participants to enroll in this study.

Risks & Discomforts

Privacy and Confidentiality
Our research staff will make every effort to protect your privacy. However, the primary risks presented by this research study are breaches of privacy (others outside of the study finding out you are a participant) and/or confidentiality (others outside of the study finding out what you did, said, or information that was collected about you during the study). Our efforts to keep your personal information confidential are described in "Protected Health Information" section below.

Venous Peripheral Catheter
The common risks are:

- pain at puncture site,
- bruising at puncture site
- fainting
- nausea

The rare risks are:

- skin-based bacteria may enter through the needle insertion site causing infection,
- vein irritation, pain in the hand, forearm or arm,
- tenderness and swelling around the puncture site.

Phlebotomy (blood collection):
The common risks are:

- pain at puncture site
- bruising at puncture site
- fainting
- nausea

Immulina™
The risks of taking Immulina™, which is derived from Spirulina are as follows:

- Rare, but minor side effects are nausea (the most common side effect), vomiting, diarrhea, stomach pain, dry mouth, fever, chest pain or discomfort, back pain, drowsiness, headache or skin rash or itching.
- Rare, but severe side effect is allergic reaction.

We do not know how your body might respond to Immulina™. We will discuss the risks identified above with you and the chances that they will happen. There may be risks that we do not know about at this time. Unknown problems, ranging from a mild inconvenience to some severe enough to result in the rapid need for medical attention, may occur. If you experience any problems, you should report them immediately to the site study doctor, Dr. Gailen D. Marshall, Jr., MD, PhD at (601) 815-1078. This is a 24-hour phone number.

Females and Males of Reproductive Potential/Pregnancy/Lactation

The risks of Immulina™ to an unborn child are unknown. You may not be pregnant, trying to become pregnant or breastfeeding while taking part in this research study. A urine pregnancy test will be done on all women of childbearing potential before beginning the study procedures. The study sponsor will be responsible for the cost of this test.

Benefits

You may or may not receive a direct benefit from being in this research study. If you take Immulina™, it is unknown if you will experience any effects. We hope to learn information that may help others in the future.

Alternatives

The study supplement is experimental. This means that you can only receive Immulina™ by enrolling in this study. The only alternative is to not participate.

Costs

There will not be additional costs to you if you participate in this study.

Immulina ™ will be supplied by the University of Mississippi Botanical Dietary Supplements Research Center at no cost to you. Any lab tests or other procedures that are done solely for research purposes, including urine pregnancy (if indicated) and biomarker lab tests as previously described will be paid for by the sponsor of this study, National Center for Complementary and Integrative Health. Insurance companies and other third-party payers will not be billed for research procedures. Research related injuries information is available in the Research-Related Injury section.

Compensation

You will receive $500 compensation for your time participating in the study. Compensation will be in the form of a check. We will need to collect your social security number or Taxpayer Identification Number (TIN) in order to issue your compensation and for tax reporting purposes to the United States Internal Revenue Service (IRS) if we are unable to compensate you in person.

Research-Related Injury

In the case of injury or illness resulting from your participation in this study, medical treatment is available to you at the University of Mississippi Medical Center. You will be charged the usual and customary charges for any such treatment you receive.

There are no plans to pay you for any lost wages or other expenses unrelated to the cost of medical treatment resulting from research–related injury.

Voluntary Participation

Your participation is voluntary. If you decide not to participate in this study, you will not suffer a penalty or loss of benefits to which you are otherwise entitled.

Your choice to participate or not participate will have no impact on your status as an employee.

Withdrawal

You may choose to stop your participation in this study at any time. If you decide to withdraw, the information already collected about you may still be used in this

study, but additional information will not be collected. Your decision to stop your participation will have no effect on the quality of medical care you receive at the University of Mississippi Medical Center or employment standing.

There may be a small possibility that the study doctor may have to terminate your participation from the study without regard to your agreement to participate in the study. It may possibly be due to unforeseen side effects that may randomly occur. The study doctor will consider each event on a case-by-case basis.

Confidentiality

Every effort will be made to keep the information we learn about you private; however, complete, total confidentiality cannot possibly be guaranteed. Study personnel, the study sponsor, the Food and Drug Administration (FDA), the Office for Human Research Protections (OHRP) and the University Mississippi Medical Center's Office of Research and Sponsored Programs, Office of Clinical Trials, Institutional Review Board (IRB), and Office of Integrity and Compliance may review the study records.

Protected Health Information

Protected health information is any personal health information through which you can be identified. The information collected in this study includes: Name, date of birth, phone numbers, email address, mailing address, and social security number or Taxpayer Identification Number (TIN). A decision to participate in this research means that you agree to the use of your health information for the study described in this form. This information will not be released beyond the purposes of conducting this study. The information collected for this study will be kept until the study is complete. While this study is ongoing you may not have access to the research information, but you may request it after the research is completed.

You have the right to cancel this authorization at any time by providing the study doctor, Dr. Marshall, with a written request to cancel the authorization. If you cancel this authorization, medical information and records about you that were created before the authorization was cancelled will be used and deidentified.

Questions

If you have questions about this study or need to report any problems, side effects, or injuries, please call Dr. Gailen D. Marshall, Jr. at (601) 815-1078. This phone line is available 24-hours a day.

You may discuss your rights as a research participant with the Chairman of the University of Mississippi Medical Center's Institutional Review Board, 2500 North State Street, Jackson, Mississippi 39216; telephone, (601) 984-2815; facsimile, (601) 984-2961. The Institutional Review Board is a group of people not involved with this study who have reviewed the study to protect your rights.

A description of this clinical trial will be available on *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.

Upon request, we will give you a copy of this consent document to review before you sign. If you choose to participate in this study, you will receive a signed copy of this document.

Statement of Participation

I have been told about this study, including the experimental treatment I may receive, and possible risks and benefits. I agree to participate in this study, to follow instructions, and to report any side effects to my study doctor. My participation is voluntary, and I may withdraw at any time without any penalty or loss of benefits to which I am entitled, including medical care at the University of Mississippi Medical Center.

By signing this form, I am not giving up any legal rights I may have.

_____
Participant's Printed Name

_____
Participant's Signature

_____
Date

_____
Printed Name of Person Obtaining Consent

_____
Signature of Person Obtaining Consent

_____
Date

I acknowledge that the participant identified above has been entered into this study, with properly obtained informed consent.

_____
Signature of Investigator

_____
Date

ADDENDUM TO MAIN STUDY CONSENT

CONSENT FOR STORAGE AND FUTURE USE OF SAMPLES

We would like to keep and store left over samples of your blood and urine to use in future research. The samples of blood and urine will be coded and stored in a freezer located at University of Mississippi Botanical Dietary Supplements Research Center laboratory in University, MS. Your name will not be on the sample, but a separate list will be created with your name and an identification code that is placed on the sample. The list of names and codes will be kept in a separate, password protected electronic file that is only accessible by the researchers.

We may use the samples to help us:

- Identify additional unknown biomarkers found in human blood or urine of volunteers who have consumed Immulina™ that may assist to optimize the design of future human interventional studies.

It is your choice. You do not have to let us do this and there will be no penalty if you do not let us keep the left over samples. This part of the study is **optional** and you can be in the study no matter what you decide. Please initial your response(s); there can be more than one response.

_____ You may keep, store and use samples of my blood and urine for future research studies to identify additional unknown biomarkers for Immulina™.

_____ You may keep, store and use samples of my blood and urine for future research studies conducted by Dr. Marshall, the study doctor or University of Mississippi Botanical Dietary Supplements Research Center. The studies do not have to be related to identifying additional unknown biomarkers for Immulina™.

_____ You may not keep, store and use samples of my blood for any future research studies.

_____

Printed name of Participant

_____ _____

Signature of Participant Date

Future Studies: We may be doing more research studies like this one in the future. If we do, may we contact you by phone or email to see if you might be interested in participating?

Please initial your choice below and complete the contact information. Phone:____Yes____No

Phone Number: _____

Email: _____Yes _____No

Email address: _____