

Informed Consent

Exclusions

If any of the following is true for you, then you may not participate in this study:

- An unusual sleep routine (examples: working graveyard shift, irregular routine with frequent late nights, studying, partying).
- Cancer during past 12 months.
- Chemotherapy during past 12 months.
- Currently experiencing intense stressful events/life changes.
- Currently in intensive athletic training (such as marathon runners).
- Currently treated with immune suppressant medication.
- Diagnosed with autoimmune disorders e.g. systemic lupus erythematosus, hemolytic anemia.
- Donation of blood during the study or within the 4 weeks prior to study start.
- Have received a cortisone shot within the past 12 weeks.
- Immunization during last month.
- Currently taking antipsychotic, hypnotic, or anti-depressant prescription medication
- Ongoing acute infections (including teeth, sinus, ear, etc.).
- Participation in another clinical trial study during this trial, involving an investigational product or lifestyle change.
- Anxiety about having blood drawn.
- Previous major gastrointestinal surgery (absorption of test product may be altered) (minor surgery not a problem, including previous removal of appendix and gall bladder).
- Taking anti-inflammatory medications on a daily basis.
- Unwilling to maintain a constant intake of supplements over the duration of the study.
- Women of childbearing potential: Pregnant, nursing, or trying to become pregnant.
- Known food allergies related to ingredients in active test product or placebo:
 - Mushrooms
 - Rosemary
 - Aloe

Please initial on the line to indicate that you have read the reasons above for not being able to participate in the study, and that none of these reasons apply to you: _____

Research study

You are invited to participate in a research study that evaluates the effects of nutritional supplements on immune cells in the blood circulation. The following information describes the study and your role as a participant. Dr. Gitte Jensen will answer any questions you may have.

APPROVED

AUG 13 2021

ARGUS IRB, INC.

July 1, 2021 Version 1.0

Purpose of this study

The purpose of this clinical study is to evaluate rapid effects on immune cells after consuming a test product. At NIS Labs, we have previously shown rapid effects of many types of natural products, where increased levels of immune cells were seen in the blood within a few hours of consumption.

Procedure

24 people will participate in the study. If you agree to participate, you will come to NIS Labs on 2 separate days, one week apart. On each visit, you will be at NIS Labs for approximately 4 hours. During that time, we will draw 4 blood samples.

Below is a list of what you will need to do:

Each morning before your study visit:

- Eat a small, bland breakfast (for example oatmeal, eggs, toast), and choose a similar breakfast for the second clinic day.
- If you need tea, coffee, soft-drinks, or nicotine in the morning, please finish this at least an hour before coming to NIS Labs.
- Do not take any nutritional supplements that morning.
- Do not exercise that morning.

On each study visit:

- Turn off your cell phone, and sit restfully in a comfortable, un-excited state of being slightly bored.
 - You may read magazines or books of a neutral, unstimulating nature.
 - You may not listen to music, chew gum, or eat candy.
- After an hour, we will draw the first blood sample.
- You will consume a test product.
- We will draw a blood sample at 1 hour after you have consumed the test product.
- We will draw a blood sample at 2 hours after you have consumed the test product.
- We will draw a blood sample at 3 hours after you have consumed the test product.

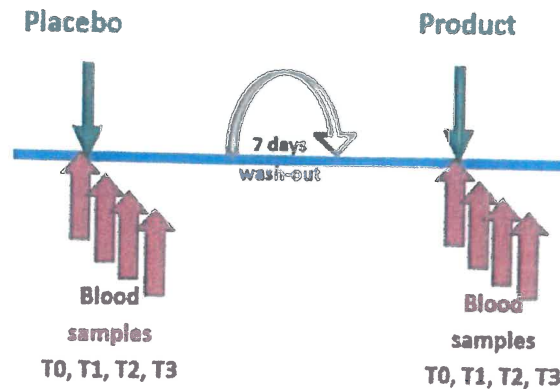
For each blood draw, 1 tube of blood will be collected (approximately 1 tablespoon), so the total blood drawn on a clinic day is 4 tablespoons. The blood will be used for counting different types of immune cells in your blood circulation and see whether some of the immune cells show signs of increased alertness. The blood will also be used for testing of plasma proteins involved in immune function and inflammation.

APPROVED

AUG 13 2021

ARGUS IRB, INC. July 1, 2021 Version 1.0

Below is a diagram showing what happens during the study. The shown sequence is an example only; the sequence in which you will consume the active test products or placebo will be randomized.



Discomforts and risks

There are no known risks to consuming the test product, except if you have allergies to certain foods. Therefore, we ask you to let us know if you have food allergies or food insensitivities to aloe, rosemary, or mushrooms.

The discomfort you may experience as a result of participating is the blood sampling, where there is a slight risk of bruising.

Benefits to participants

There is no direct benefit to you from participating in this study. We are not focusing on your personal health, but on subtle changes in your body after consuming the test product. If the test product is found to have a positive effect on the immune system, you will have contributed to this scientific knowledge. This may benefit you or others in the future.

Remuneration

A compensation of \$180 will be offered for the participation in this study, that includes the two 4-hour visits with 4 blood draws per study day.

Should you decide to discontinue your participation between the first and the last study day, you will be reimbursed \$60 for the initial study day you participated.

Should you have any questions before, during, or after the study is completed, you may contact Dr. Gitte Jensen: 541-884-0112. If you have questions regarding your rights as they relate to your participation in

APPROVED

AUG 13 2021

July 1, 2021 Version 1.0

ARGUS IRB, INC.

NIS Labs Study 181-002 Rapid immune modulating effects:
Clinical Proof-of-Concept Study

Date: _____
Study Participant #: _____

this study, you may contact ARGUS Institutional Review Board (which is a group of people who review research to protect your rights) Owner, Valerie Golembiewski: 520-298-7494.

Confidentiality

Only Dr. Gitte Jensen and the immediate study coordinator and research assistants during the study will have access to any confidential data which identifies you by your first and last name. All other investigators and staff involved in testing during this study will know you only by a number code. You may choose to let your family doctor know that you are participating in this study. Your participation in this study is voluntary, and you may discontinue your participation at any time.

Authorization

I have read and understood the information provided. I have been given the opportunity to discuss this information with my doctor and study personnel and have had my questions answered in language I understood. I meet all the study criteria. The risks and benefits have been explained to me. I understand that I will be given a copy of this consent form after signing it. I freely agree to participate in this study.

I understand that my participation is voluntary and that I may withdraw from the study at any time after signing this form without penalty. I also understand that I may be withdrawn from the study for non-compliance, or if it is determined that it is in my best interests to do so. I agree to abide by all subject instructions, reminders, and precautions given to me before and during the study.

Participant

SIGNATURE OF PARTICIPANT

PRINT NAME

DATE

NIS Representative

SIGNATURE OF NIS REPRESENTATIVE

PRINT NAME

DATE

APPROVED

AUG 13 2021

ARGUS IRB, INC.

July 1, 2021 Version 1.0