Columbia University Consent Form

Protocol Information

Attached to Protocol: IRB-AAAR8427
Principal Investigator: Emily Dimango (ead3)
IRB Protocol Title: Ginger's therapeutic potential in asthma

General Information

Consent Number: CF-AACA1150
Participation Duration: 78 days
Anticipated Number of Subjects: 36
Research Purpose: The purpose of this study is to test the effect of oral ginger on airway hyper responsiveness and inflammatory cell mediators in adult patients with Asthma.

Contacts

Contact	Title	Contact Information
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Information on Research

WHAT INFORMATION IS IN THIS FORM?

The purpose of this form is to give you information to help you decide if you want to take part in a research study. This consent form includes information about:

- why the study is being done;
- the things that you will be asked to do if you are in the study;
- any known risks involved;
- any potential benefit;
- options, other than taking part in this study, that you have.

The principal investigator (the lead researcher for this project) will discuss the study with you. If at any time you have questions about the study, please ask a member of the study team. Take all the time you need to decide whether you want to take part in this research study.

We are asking you to take part in a research study.

This form explains why we are doing this study and what you will be asked to do if you choose to be in this study. It also describes the way we (Researchers) would like to use and share information about you. Please take the time to read this form. We will talk to you about taking part in this research study. You should ask us any questions you have about this form and about this research study.
You do not have to participate if you don't want to.

WHY IS THIS STUDY BEING DONE?

We are doing this research study to find out if an herbal supplement, ginger, can help people who have asthma. We are trying to understand if ginger reduces inflammation in the airways of people with asthma.

WHAT WILL I BE ASKED TO DO IF I CHOOSE TO BE IN THIS STUDY?

We will ask you to come to the Asthma Center in Presbyterian Hospital.

We will ask you to complete 3 surveys.

If subjects qualify for the study, you will be randomized to take either ginger capsules twice per day or placebo capsules twice per day for 56 days.

We will ask you to give a blood sample of two teaspoons of blood 3 times over the nearly 3 months of the study. Blood will be drawn by the study physician or the study coordinator at the study center from a vein in your arm, after the area is cleaned with an alcohol swab. The blood will be drawn by the study staff and sent to the clinical laboratory at Columbia or to a research laboratory.

If you consent to participate in the PK sub-study, you will be asked to withhold your study drug at Visits 4 and 5.

If you test positive for COVID-19 at any point of the study, you will be terminated early.

Note: All methacholine bronchoprovocation procedures (on visits 2, 4, and 5) have been removed from the study visits due to the Covid-19 pandemic.

The following tests and procedures will be done on scheduled visits:

Covid-19 Nasal swab test 1: 1-3 days before Visit 1.

Day 0/Visit 1: Screening Visit: review of medical history, recording of medication use, physical exam by study MD or NP and pulmonary function test (spirometry) before and 15 minutes after inhaling four puffs of a short acting bronchodilator. You will then be asked to continue your usual asthma medications for the 14-21 day screening period.

You will be asked to complete a questionnaire.

Day 14-21/Visit 2: You will be asked to complete one questionnaire. You will be asked to withhold some of your inhalers for a pre-specificed time (withhold albuterol for at least 6 hours and withhold long acting bronchodilator for at least 24 hours). Women of child bearing potential will have a urine pregnancy test checked. You will undergo spirometry, and then a methacholine bronchoprovocation testing which involves inhaling increasing concentrations of nebulized methacholine and closely monitoring your lung function to determine the dose that causes a 20% drop in lung function.
Note: Study Visit 2 has been eliminated due to Covid-19 pandemic.

Covid-19 Nasal swab test 2: 1-3 days before visit 3.

Day 15-24/Visit 3 Randomization Visit:
1-3 days after the methacholine testing, you will be randomized (similar to flipping a coin) into one of two treatment groups; oral ginger (1 g twice per day: Pure Encapsulations™) or matching placebo. You will be asked to take 2 capsules, each containing 500 mg of ginger, or placebo each morning and evening for 56 days.
At this visit, pulmonary function (spirometry) will be measured, women of child bearing potential will have a pregnancy test confirmed, you will be asked to complete three questionnaires about your asthma symptoms. We will measure inflammation in your lungs by asking you to breath into a machine that measures a gas called nitric oxide. 10 ml (two teaspoons) of blood will be collected from a vein in your arm for measurement of mediators which serve as markers for inflammation in your lungs. You will then be given your first dose of study drug and the breathing test (spirometry) will be repeated one hour later. PK samples will be collected to measure ginger compounds in the blood, with another 35 ml of blood from select subjects.

Covid-19 Nasal swab test 3: 1-3 days before visit 4.

Day 43-50/Visit 4: At this visit, pulmonary function (spirometry) will be measured, women of child bearing potential will have a pregnancy test confirmed, you will be asked to complete three questionnaires about your asthma symptoms. We will measure inflammation in your lungs by asking you to breath into a machine that measures a gas called nitric oxide. 10 ml (two teaspoons) of blood will be collected for measurement of inflammation in your lungs. A breathing test (methacholine challenge) will be performed. You will then be given a dose of study drug. PK samples will be collected to measure ginger compounds in the blood, with another 35 mL of blood from select subjects.

Covid-19 Nasal swab test 4: 1-3 days before visit 5.

Day 71-78/Visit 5:
At this visit, pulmonary function (spirometry) will be measured, women of child bearing potential will have a pregnancy test confirmed, you will be asked to complete three questionnaires about your asthma symptoms. We will measure inflammation in your lungs by asking you to breath into a machine that measures a gas called nitric oxide. 10 ml (two teaspoons) of blood will be collected to test for mediators that serve are markers of inflammation in your lungs. You will then be given a dose of study drug. PK samples will be collected to measure ginger compounds in the blood, with another 35 ml of blood from select subjects.

If you agree to a separate part of the study, we will collected an additional 35 ml (7 teaspoons) of blood from a vein in your arm over 8 hours, at 6 additional time points, to measure the level of medication in your blood. This will occur at visits 3, 4 and 5, for a total of 105 ml.

____ I agree to participate in this separate study

____ I do not agree to participate in this separate study

_____Print name and date

Risks

WHAT ARE THE RISKS OF THE STUDY?

General risks

There may be risks or discomforts if you take part in this study. These include:

COVID-19 Testing: A diagnostic test is performed by inserting a swab into your nose and twirling it around for a few seconds. The swab sample will then be sent to the lab for results. Some subjects may experience a lachrymal reflex, which may cause teary eyes as well as some minor discomfort.

Pulmonary Function Testing: This test requires deep and forceful respiratory efforts. It is a commonly performed and safe examination that is widely performed in patients with lung disorders. Some patients report chest soreness the day following the procedure. Some patients may experience light-headedness during the forced expiration. The risk of syncope is mitigated by having the patient perform the test in the seated rather than standing position.

Methacholine challenge involves the inhalation of an agonist to induce bronchoconstriction and may induce the symptoms of an asthma exacerbation (chest tightness, dyspnea, coughing). The procedure is performed in a closely monitored clinical environment, with availability of bronchodilator. This procedure has been safely used in many previous studies in our division and nationwide, we will only perform this procedure if your baseline lung function is greater than a certain cutoff of 60%.
Note: Methacholine challenge tests have been removed from study visits 2,4, and 5 due to the Covid-19 pandemic.

Bronchodilator (albuterol/salbuterol) will be available to be administered if you are uncomfortable from the effects of the methacholine challenge test. These drugs can lead to tremor, nervousness, tachycardia, palpitations and headache – these reactions are transient and rare (<5%) with the proposed doses used for this study, and if they occur, we will monitor you until you feel better. High doses may cause arrhythmias and low potassium: these are very unlikely with the doses used for this study.

Questionnaires and assessments: You will be asked to provide information about your psychological, physical, and medical functioning on questionnaires. The mini asthma quality of life questionnaire consists of 15 questions for which

you will be asked to check a scale of 1 to 7. This questionnaire takes approximately 10 minutes to complete. The Asthma Control Test ("ACT") consists of 5 questions and takes less than 5 minutes to complete. The Asthma two week recall (A2WR) has four questions regarding your asthma symptoms in the past two weeks and should take you less than 5 minutes to complete.

Side effects of medication: Some previous studies of ginger have reported mild gastrointestinal side effects such as bloating. If you experience these side effects, please let your study team know.

Drug interactions: It is possible that ginger can intensify the effect of anti coagulation drugs (eg blood thinners). Only subjects not taking anticoagulants will be enrolled in the study. If for some reason, your doctor prescribes anti-coagulation therapy, you will be withdrawn from the study.

While we will make every effort to protect privacy and keep data confidential, there is a risk that information can be disseminated in ways that can risk the privacy of a person. To minimize risk, we will use only study codes to identify data and study records, store study data and records in a secure place, and personal information such as names, addresses, and telephone numbers will not be in the central database.

Venous Blood Draw: For each blood draw, approximately 10 ml (2 teaspoons) of venous blood will be drawn from your arm. Blood drawing may cause a small amount of pain. In addition, a temporary bruise may develop. Rarely, people faint after blood drawing. Very rarely, the vein in which the needle has been inserted may become inflamed or infected. Samples will be identified only by alphanumeric identifiers.

Exhaled NO (FeNO): Exhaled breath will be collected from forced expirations using disposable mouthpieces so that we may measure inflammation in your lungs. There are no known risks involved with breathing into the collection system.

There may be other risks of taking part in this research study that we don't know about. If we learn about other risks, we will let you know what they are so that you can decide whether or not you want to continue to be in the study.

Benefits

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

Potential direct benefit

You may or may not receive personal (direct) benefit from taking part in this study. The possible benefits of taking part in this study include a possible improvement in asthma symptoms if the study medication is in fact helpful for asthma.

There may be no direct benefit for taking part in this research study,

You may not receive personal (direct) benefit from taking part in this research study, however the information collected from this research may help others in the future.

Alternative Procedures

WHAT OTHER OPTIONS ARE THERE?

You may choose not to take part in this research study.

You do not have to take part in this study to get treatment for your condition. The alternative to participating in this study is not participating in the study.

Confidentiality

WHAT ABOUT CONFIDENTIALITY?

Any information collected during this study that can identify you by name will be kept confidential. We will do everything we can to keep your data secure, however, complete confidentiality cannot be promised. Despite all of our efforts, unanticipated problems, such as a stolen computer may occur, although it is highly unlikely.

Your data, biological samples, questionnaire responses and health information will be assigned a code number, and separated from your name or any other information that could identify you. The research file that links your name to the code number will be kept on a password-protected computer and only the investigator and study staff will have access to the file.

The following individuals and/or agencies will be able to look at and copy your research records
- The investigator, Columbia University staff, New York Presbyterian Hospital staff and other medical professionals who may be evaluating the study
-Columbia University Medical Center has recently implemented a new electronic medical record (EMR) system, which will be shared with Weill Cornell Medical Center and New-York Presbyterian Hospital and its affiliated institutions. Your participation in this research study will be documented in our new EMR system. Medical records in this system can be viewed by authorized personnel from these institutions. Study monitors and others who provide oversight of the study may also need to access this record.
- Authorities from Columbia University including the Institutional Review Board ('IRB'), and other regulatory agencies
- The Office of Human Research Protections ('OHRP') and the United States Food and Drug Administration ('FDA');
- the sponsor of this study, [the National Institutes of Health], including persons or organizations working with or owned by the sponsor

Research Related Injuries

WHAT IF I GET HURT WHILE I AM ON THE STUDY?

Taking part in this research study may result in injury or harm to you. In the event of an injury resulting from your participation in this study, you should seek appropriate medical care and inform the study doctor. In the event of an

emergency you should go to an emergency room.

If you are injured or harmed as a result of participating in the study and receive medical care through the NewYork-Presbyterian Hospital (NYPH), a Columbia doctor, or any other health provider, you will be sent a bill for whatever medical care you receive. All or part of your bill may be paid by your health insurance.

Columbia University and NewYork-Presbyterian Hospital (NYPH) are not offering to provide you the drug after the termination of the study or to pay you for pain, worry, lost income, the cost of your medical care or non-medical care costs that might occur as a result of your taking part in this study. However, you do not waive any of your legal rights in signing this form.

Compensation

WILL I GET COMPENSATED?

You will be compensated for your participation in the study as outlined below. There are 5 study visits (note: study visit 2 has been eliminated) and 4 COVID-19 testing visits. If you complete all study visits (visit 2 excluded), including COVID-19 testing, you will get a total of $300. If you are part of the PK study, you will get a total of $595. If you miss any of the visits, you will not be compensated for those visits. If you terminate the study early, you will receive an amount based on the visits that you have completed. Payment for each visit will be in the form of a pre-loaded credit card that will be given to you. Reimbursement will be processed after completion of both covid-19 nasal swab and subsequent study visit. If a subject has only completed a COVID-19 testing visit and cannot complete the subsequent visit, he/she will be compensated $25.

Covid-19 Nasal Swab 1: $25
Visit 1: $50
Visit 2: $50 (Eliminated)
Covid-19 Nasal Swab 2: $25
Visit 3: $50
Covid-19 Nasal Swab 3: $25
Visit 4: $50
Covid-19 Nasal Swab 4: $25
Visit 5: $50

Additional Costs

WHAT ARE THE COSTS?

No cost

There are no costs to you for taking part in this study.

Taking part in this study will not involve additional costs to you. All study drugs will be given free of charge by the sponsor. You and/or your insurance company will have to pay for any costs that are part of your regular medical care.

You will remain responsible for all insurance premiums, deductibles, copayments, and coinsurance amounts.

Voluntary Participation

DO I HAVE TO BE IN THE STUDY?

Voluntary Participation

Participation in this study is voluntary. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. You may discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled.

This consent also confirms your permission for the study team to contact you by email or phone during the study to encourage your compliance. Please verify with the research team which method of contact would be best for you.

Additional Information

WHAT CAN I EAT WITH THE STUDY DRUG?

We will be asking you to withhold eating foods that have high polyphenols, due to its interaction with Ginger. This will include coffee, tea, fruits, vegetables, juice and supplement intakes of food. A full list of foods and drinks to avoid will be provided to you by the research coordinator. We will only ask you to withhold this food up to three days before your visits 4 and 5

Food will be provided for those who are dosing with study drug in clinic.

Statement of Consent

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I have read the consent form and talked about this research study, including the purpose, procedures, risks, benefits and alternatives with the researcher. Any questions I had were answered to my satisfaction. I am aware that by signing below, I am agreeing to take part in this research study and that I can stop being in the study at any time. I am not waiving (giving up) any of my legal rights by signing this consent form. I will be given a copy of this consent form to keep for my records.

Signatures

Participant Signature Lines

Study Subject

Print Name _____ Signature _____

Date & Time _____

Research Signature Lines

Person Obtaining Consent

Print Name _____ Signature _____

Date & Time _____