CHANGE COVID-19 Severity

NCT04941703

Informed Consent Form

Document Date: 5/17/2022

Study Title: Investigation of Choice Alteration of Gut Metagenome on COVID-19 Severity
Version Date: September 20, 2021
PI: Wonder Drake, MD

Name of participant: _____ Age: _____

The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.

Key Information:
The first section of this document contains some key points that the research team thought you would find important. The study is described in more detail after this section. If you do not understand something, please ask someone.

Key information about this study:
Several studies reports that patients who come into the hospital with COVID-19 have bad bacteria in their colon. This is a study to determine if getting rid of bad bacteria in the colon of COVID-19 patients will help them breath better. This research study is being done to determine if taking oral magnesium citrate and a probiotic, Floranex, will improve the outcome of adults hospitalized with COVID-19. In this study, half of the participants will receive magnesium citrate plus a probiotic Floranex and half will receive a placebo (a harmless substance that will mimic the look, taste, and consistency of the real study drugs). The magnesium citrate may cause you to pass stool; the probiotic Floranex may change the bacteria in your colon. You will be placed in one of these 2 groups randomly, like the flip of a coin. You, your hospital care team, and the study staff will not know if you are taking the real medicine or the placebo.

If you decide to enroll in this study, you will receive either placebo drink (carbonated lemon water) and capsules (microcrystalline capsules) or one 10 oz bottle of magnesium citrate to drink once and 2 oral Floranex capsules to be taken twice a day for 6 days. If you do not have sufficient movement of your bowels, you will receive a second bottle of magnesium citrate or placebo. We will also collect two blood samples from you (day 1 and day 7), two nasal swabs (day 1 and day 3) and we will be collecting information about you and your COVID-19 infection progression while you remain hospitalized.

We will coordinate with your hospital care team throughout the study. Assessments for this study will be done on day 7 and day 29 if you are still hospitalized at those time points. If you are discharged from the hospital before the day 7 or day 29 assessments, we will do these with you by phone. You will also be contacted at 3 months to assess how you are doing. There will be no cost to you for taking part in this study.

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Detailed Information:
The rest of this document includes detailed information about this study (in addition to the information listed above).

You are being asked to take part in this research study because you have been hospitalized with COVID-19 infection. You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services, or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study. Your medical record will contain a note saying you are in a research study and may contain some research information about you. Anyone you authorize to receive your medical record will also get this information.

Side effects and risks that you can expect if you take part in this study:

Magnesium citrate

Common side effects (~10%) include abdominal cramping, diarrhea electrolyte imbalance, gas (flatulence), nausea, vomiting and high magnesium levels in the blood.
Rare side effects (~ 3%) associated with high blood levels of magnesium can include muscle weakness, decrease in tendon reflexes, mental confusion, sedation, slowed respiratory rate, low blood pressure, slowed heart rate intestinal blockage, and low blood calcium levels.
Extremely Rare side effects associated with very high blood levels of magnesium can include profound mental depression, lack of muscle reflexes, coma, respiratory paralysis and even death.
Some of these side effects may require additional medications or medical interventions in people who have poor kidney function.

Probiotic Floranex

Common side effects include gas, bloating, diarrhea and allergic reaction, including hives, chest tightness, difficulty breathing, swelling of your face, lips, tongue, or throat.

Good effects that might result from this study:
You could possibly have an improved COVID-19 infection outcome. There may also be benefits to science and humankind that result from this study.

Procedures to be followed:

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Pre-Enrollment through Randomization:

- We will test you for pregnancy if you are of child-bearing potential.
- 2 Blood samples collected 30 mL (2 tablespoons) for +immune cells
- Nasal Swab test SARS CoV-2 on day 1 and day 3.
- COVID Ordinal Outcomes Scale scored –measure of how sick you are due to COVID-19
- Sequential Organ Failure Assessment scored -measure of how sick you are due to COVID-19
- Acute Respiratory Distress Syndrome assessment-measure of how sick you are due to COVID-19
- Collection of Data at baseline:
  - Demographic
  - Signs and symptoms
  - Medications
  - Medical history
  - Hospital admission information
  - Oxygen and ventilation status
- Randomization to a study group

Other Assessments While Hospitalized:

- Study Drug Adherence Assessment (days 1-6)
- Blood sample collected 30 mL (2 tablespoons) for immune cells(day 7)
- Nasal Swab test SARS CoV-2 (day 3)
- COVID Ordinal Outcomes Scale scored (daily)
- Sequential Organ Failure Assessment scored (day 3)
- Acute Respiratory Distress Syndrome assessment (daily)
- Assessment of Antibiotic Used (days 2-7)
- Study Data Collection:
  - Assess for clinical diagnosis of blood clots in your legs or lungs
  - Oxygen/Ventilation assessments (how well you are breathing every day)
  - Medication assessments (which medications you are taking daily)
  - Date and time of first meeting the ARDS Berlin Diagnostic Criteria (if applicable)
  - ICU admission/discharge (if applicable)
  - Report of death (if applicable)
  - Safety Outcomes
  - Hospital discharge

After Discharge:

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- 3-month follow-up visit by phone to see how you are doing.

If you are discharged before evaluations for days 7 or 29, these evaluations will be conducted by phone where possible.

Costs to you if you take part in this study:

There is no cost to you for taking part in this study.

Payment in case you are injured because of this research study:
If it is determined by Vanderbilt and the Investigator that an injury occurred as a direct result of the tests or treatments that are done for research, then you and/or your insurance will not have to pay for the cost of immediate medical care provided **at Vanderbilt** to treat the injury.

There are no plans for Vanderbilt to pay for any injury caused by the usual care you would normally receive for treating your illness or the costs of any additional care. There are no plans for Vanderbilt to give you money for the injury.

Who to call for any questions or in case you are injured:
If you should have any questions about this research study or if you feel you have been hurt by being a part of this study, please feel free to contact Wonder Drake, MD at 615-322-2035**.** If you cannot reach the research staff, please page the study doctor at 615-835-5076.

For additional information about giving consent or your rights as a person in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to call the VUMC Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

Reasons why the study doctor may take you out of this study:
If the study doctor and/or your care team determine it is in your best interest you may be removed from the study.

What will happen if you decide to stop being in this study?
If you decide to stop being part of the study, you should tell your study doctor. Deciding to not be part of the study will not change your regular medical care in any way.

Clinical Trials Registry:

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A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this Web site at any time.

Confidentiality:
The information (paper forms) containing identifiable information we collect from you will be stored in a file cabinet of a locked office by the research study staff. Only the study staff will have access to your information. To maintain confidentiality, all laboratory specimens, evaluation forms, and reports entered into the study database will be identified only by a coded number. They will not contain information that can identify you. The coded number will be generated by the study staff in sequential order (001, 002, etc.), and only the study staff will have access to the codes. All electronic records will be kept in a locked, password protected computer. All computer entry and networking programs will be done with coded numbers only.

The NIH or Vanderbilt may share your information, without identifiers, to others or use it for other research projects not listed in this form. The NIH, Vanderbilt, Dr. Drake and her staff will comply with any and all laws regarding the privacy of such information. There are no plans to pay you for the use or transfer of this de-identified information.

For your protection this study will be monitored to ensure it is being conducted according to the protocol and in an ethical manner. This monitoring may include the following:

- An in-person monitor will review your study information
- Your medical information collected for this study will be uploaded to the Vanderbilt Redcap database. Access to this database will be strictly limited to study staff only and is a very reliable and secure research database.

This study may have some support from the National Institutes of Health (NIH). If so, your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.

It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

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Privacy:
Any samples and information about you may be made available to others to use for research. To protect your privacy, we will not release your name. You will not receive any benefit as a result of the tests done on your samples. These tests may help us or other researchers learn more about the causes, risks, treatments, or how to prevent this and other health problems.

Authorization to Use/Disclose Protected Health Information
What information is being collected, used, or shared?
To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers (including both Vanderbilt University Medical Center and others) may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

Who will see, use or share the information?
The people who may request, receive or use your private health information include the researchers and their staff. Additionally, we may share your information with other people at Vanderbilt, for example if needed for your clinical care or study oversight. By signing this form, you give permission to the research team to share your information with others outside of Vanderbilt University Medical Center. This may include the sponsor of the study and its agents or contractors, outside providers, study safety monitors, government agencies, other sites in the study, data managers and other agents and contractors used by the study team. We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

Do you have to sign this Authorization?
You do not have to sign this Authorization, but if you do not, you may not join the study.

How long will your information be used or shared?

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Your Authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies.

What if you change your mind?
You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let them know by using the contact information provided in this consent form. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

I have read this consent form and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to take part in this study.

_____ _____
Date Signature of patient/volunteer

Consent obtained by:

_____ _____
Date Signature

Time: _____ _____
Printed Name and Title

Surrogate Consent (if applicable)

I, _____ [name of decision-maker/surrogate],
am the _____ [state relationship to participant]

Date of IRB Approval: 05/17/2022
Date of Expiration: 05/16/2023

Institutional Review Board

VANDERBILT

This box is for IRB USE ONLY
Do not edit or delete

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of _____ [state participant's name]. I have read the informed consent document, or it has been explained to me. I have had the opportunity to ask any questions and all of my questions have been answered. I have been informed that an investigational treatment may be administered to _____ _____ [participant's name]. I believe receiving such treatment would be in the interests of _____ [participant's name] and is consistent with what he/she would have decided had he/she been able to do so.

Your decision to allow your family member/friend to participate in this research study is voluntary. You may choose not to allow his/her participation and he/she will receive alternative treatments without affecting his/her healthcare/services or other rights. You are also free to withdraw him/her from this study at any time. In the event new information becomes available that may affect the risks or benefits associated with this research study or your willingness to allow continued participation in this research study, you will be notified so that you can make an informed decision whether or not to continue your family member/friend's participation in this study.

Your family member/friend will periodically be re-evaluated for the capacity to give consent. If he/she is found to be capable, continued participation in this study would only occur with his/her consent.

_____ ___/___/___
Signature of Legally Authorized Representative/Surrogate Date

_____ ___/___/___
Signature of Witness Date

_____ ___/___/___
Name and Signature of person obtaining consent Date