Northwell Health

Consent for Participation in a Research Study

Study Title: A Multi-site, Randomized, Double-Blind, Comparative Trial of the Safety and Efficacy of Famotidine vs Placebo for the Treatment of Non-Hospitalized symptomatic Adults with COVID-19

Principal Investigator: Tobias Janowitz, MB, BChir, PhD

About this research
You are being asked to participate in a research study.

This consent form will give you information about the study to help you decide whether you want to participate. Please read this form, and ask any questions you have, before agreeing to be in the study.

Important Information
This information gives you an overview of the research. More information about these topics may be found in the pages that follow.

Why am I being asked to provide my consent?	This is a research study, which is different than routine medical care. Scientists do research to answer important questions which might help change or improve the way we do things in the future.
Do I have to join this research study?	No. Taking part in this research study is voluntary. You may choose not to take part in the study or may choose to leave the study at any time. Deciding not to participate, or deciding to leave the study later, will not result in any penalty or loss of benefits to which you are entitled.
Why is this research study being done?	The purpose of this research study is to find out if famotidine is a safe and effective treatment against COVID-19. Famotidine is a medication commonly used to treat other illnesses.
What will happen to me during the study?	During this study, you will be given famotidine or placebo. In addition, you will be mailed a study kit which will include an electronic tablet, accessories to measure your vitals and the study medication. You will have to participate in several virtual visits with a study investigator during the course of the study. We will use the electronic tablet to communicate with you and send a phlebotomist to your house to draw blood and do a nasal swab. You will be provided with a Fitness tracker to wear for the duration of the study that monitors your movement (steps). You will be asked to take medication at home and take your temperature and weight. You will be asked to measure your ability to breathe (lung function) and the levels of oxygen in your blood using simple devices that will be provided to you.

How long will I participate?	You will be in this study for a total of 60 days. You will receive medication to take at home for up to 14 days. If you are pregnant while participating in this study, we will follow up with you for 12 months after the expected due date.
Will taking part expose me to risks?	Taking any medication exposes you to a risk of side effects. There is a small risk of headache, dizziness, constipation or diarrhea when taking Famotidine. With any research study that collects personal information, there is a small risk of loss of confidentiality.
Are there any benefits to participation?	If the medication being studied is effective against COVID-19, participation in this research study may benefit you directly. Information learned in this study will help us to better treat future patients.
What are my alternatives to participation?	If you do not participate in this study, you will not receive the medication being studied. However, you can take famotidine without participating in this study.

Please review the rest of this document for details about these topics and additional things you should know before making a decision about whether to participate in this research.

Introduction
You are being asked to join a research study. The purpose of a research study is to answer specific questions, sometimes about the safety of a drug or device and how well it works. Being in a research study is different from being a patient. When you are a patient, you and your doctor have freedom in making decisions about your healthcare. When you are in a research study, the researcher will follow the rules of the research study as closely as possible, while monitoring your health.

You do not have to be in this study to receive medical care. You should ask questions before you decide if you want to participate. You can also ask questions at any time during the study.

Why is this research study being done?
There is no vaccine or medication currently approved for the prevention or treatment of COVID-19 in patients who are not admitted to hospital. The purpose of this research is to find out if famotidine is effective against COVID-19.

Why is this research?
This is a research study because the medication being studied has not been used to treat COVID-19 before. Famotidine is FDA-approved to treat other illnesses, but it has not yet been proven effective in patients with COVID-19. Famotidine is considered investigational in this study.

You are being asked to participate in this study because you have been diagnosed with COVID-19

How many people will take part in this study?
This research study hopes to enroll a total of 84 people.

How long will you be in this study?

If you choose to take part in this study, the study procedures will last for about 28 days after study entry. You will take medication for up to 14 days.

What will happen in this research study?
In this study you will be randomized to one of two different treatment groups. This means that you will be assigned to a group by chance (like flipping a coin). You will have an equal chance of being in any group. Both study groups will receive treatment. The study is done this way because knowing whether you are in a group can change the results of the study. We will not tell you which group you are in. The research study staff will not know your group either. We can quickly find out which group you are in if we ever need to know for your safety. The different treatment groups are as following:

1) Patients will receive famotidine 80mg three times daily.
2) Patients will receive placebo three times daily.

As noted above, you may receive a placebo. A placebo is a pill that looks like the study drug but has no medicine in it. It is being used so the researchers do not know which study group you are in.

You will be in this study for about 60 days. You will receive all equipment necessary to participate in the study free of charge. Medicine will be sent to your home for the first 14 days. You will be asked to record when you take it and how you are feeling on a daily questionnaire for the first 28 days and again on day 60. You will wear a Fitness tracker that will monitor your movement (steps) for the first 28 days. You will be asked to weigh yourself, and measure your body temperature, the amount of oxygen in your blood and your lung function utilizing the equipment sent to your home every day for the first 28 days. Every evening, we will review if you have filled out the questionnaire. In case you did not fill out the questionnaire, we will send a reminder and later call you to inquire if there are medical reasons for you to be unable to fill in the questionnaire. You will connect virtually with the study team through the electronic tablet at 7 days, 14 days, and 28 days of the study. We will collect the results of those and any other tests done and record them for this study. We will have a phlebotomist come to your house to draw your blood and do the nasal swab.
If you are pregnant while participating in this study, we will follow up with you for up to 12 months after your estimated due date via phone interviews at the four following time points: Once between finishing the study period and your estimated due date, at your estimated due date, and 6 and 12 months after the estimated due date.

VitalTech Kit & App

You will be able to complete the daily questionnaire through an app on the tablet you are provided. After enrolling in the study and receiving a study kit, a representative from VitalTech (the company that makes the study kits) will contact you to help you set up the tablet, the pulse oximeter, spirometer, weighing scale, and fitness tracker. The following data points will be collected through the app: your daily replies to the symptom questionnaire, the data obtained by

the scales, the pulse oximeter, the spirometer, the thermometer, and the VitalBand activity monitoring device.

The app will already be loaded on the tablet you receive. In order to use the app and participate in this study, the first time you open the app, you will register with a unique user ID and password. This process is needed to be able to register your device and allow for data to be transferred to the investigators. While registering, you will be asked to read and accept an End User License Agreement (or "EULA"). You will need to accept in order to participate in the study. The EULA will govern your relationship to VitalTech Affiliates, LLC (the manufacturer of the VitalCare application) with respect to your use of the VitalCare application. The EULA affects your legal rights. Specifically, under the EULA, VitalTech Affiliates, LLC will not be responsible for any damages, injury, or loss resulting from your use of the VitalCare application, including any damages, injury or loss due to the negligence of VitalTech Affiliates, LLC. If you wish to bring a claim or cause of action against VitalTech Affiliates, LLC you have only one (1) year to bring the claim (the clock will start when you are harmed or become aware of the harm). The terms of the EULA do not affect your rights with respect to the Study sponsor, Northwell Health.

What are the risks of the research study? What could go wrong?
Famotidine is a drug commonly used to treat acid indigestion and is usually very well tolerated. There is a risk of mild side effects including headache, dizziness, constipation and diarrhea. Other side effects that have been reported in less than 1% of patients in clinical trials with Famotidine were:

- fever,
- fatigue,
- weakness,
- heart palpitations,
- elevated liver enzymes,
- nausea,
- vomiting,
- stomach discomfort,
- loss of appetite,
- dry mouth,
- low blood platelet count,
- rash,
- swelling around the eyes,
- red eyes
- tightening of the muscles that line the airways (bronchospasms),
- muscle pain,
- joint pain,
- seizure,
- hallucinations,
- depression,

- anxiety,
- decreased libido,
- inability to sleep (insomnia),
- hair loss
- dry skin,
- flushing,
- ringing in the ears,
- taste disorder,
- impotence.

Some side effects reported since approval of Famotidine were:

- irregular heartbeats,
- interruption of impulse transmission from atria to the ventricles (AV block),
- longer than normal time for your heart to recharge between beats (prolong QT interval),
- yellowing of the skin, eyes and/or mucous membranes due to flow of bile from the liver slows or stops (cholestatic jaundice),
- inflammatory condition of the liver (hepatitis),
- reduction in number of white blood cells (agranulocytosis),
- too few red blood cells, white blood cells, and platelets (pancytopenia),
- reduced number of white blood cells (leukopenia),
- acute allergic reaction (anaphylaxis)
- swelling of the face (facial edema),
- hives or welts (urticaria),
- muscle breakdown (rhabdomyolysis),
- muscle cramps,
- confusions,
- agitation,
- pins and needles sensation (paresthesia),
- lung disease causing scaring of lung tissue (interstitial pneumonia),

Steven Johnson syndrome. (a rare disorder of the skin and mucus membranes with a painful rash that may spread In this study, famotidine is being used at higher doses than usually used to treat acid indigestion. Thus, as with any drug, there might be side effects that are unknown at this time. You will be closely watched for side effects. You should report any unusual events to the study staff.

In studies on hospitalized patients, researcher have found that there may be a risk that anti-acid medication increase risk for acquiring pneumonia and decrease the protection against viral infections.

If you have been diagnosed with deficiency of Al, Cu, Mn, Fe and Zn and take oral replacement of these minerals you will not be able to participate in this study.

If you do not want to take part in this research study, what are your other choices?

If you do not join this study, you have other choices for treatment. Talk to your doctor about your choices. Your other choices may include:

- Another research treatment
- Treatment with monoclonal antibodies
- No treatment
- Comfort care
- Famotidine without participating in this study

Your doctor can also tell you the important risks and benefits associated with the alternative treatment.

How is this study funded?
This study is funded by a grant from the FastGrant funding mechanism. The grant will cover the costs of the study drug supply, equipment acquisition, and study personnel. Neither the funding agency nor the investigators have any financial interest in developing the study drug.

What happens if you are injured while participating in this study?
If you are hurt from being in the study, you will receive medical care and treatment as needed from Northwell Health. However, you will be responsible for the costs of such medical treatment, directly or through your medical insurance or other forms of medical coverage. No money will be given to you.

What are your rights as a research participant?
Your participation in this project is voluntary. The quality of your medical care will be the same, whether you join, refuse to join, or decide to leave the study.

If you do not join the study you will not be penalized or lose benefits to which you are entitled. If you join the study you may withdraw at any time without prejudice to your future care at Northwell Health. Follow-up examinations may be needed to assure your well-being.

Could you be taken off the study before it is over?
It is also possible that your participation in this study may end without your consent. This decision may be made by a researcher, study sponsor or the Institutional Review Board (IRB- the committee that oversees research at this institution).

Reasons for withdrawal may include:

- failure to follow instructions,
- unable to participate in virtual visits through electronic tablet
- failure to provide blood or nasal swab for the necessary tests
- it is not in your best interest to continue on this study, or
- the study is stopped.

If you withdraw from this study or if you are withdrawn from the study, any data (or samples) already collected will continue to be used. However, no new data will be collected. If you withdraw from this study or are withdrawn from the study, you will keep the equipment.

What happens if new information is learned?
You will be told of any new findings that may change your decision to continue to participate. Your consent to continue to take part in this study may be obtained again.

What information will be collected and used for this study?
If you agree to be in this study, we will collect health information that identifies you. We may collect the results of tests, and medical examinations done while you are in the hospital. We may also collect information from your medical record. We will only collect information that is needed for the research. This information has been described in this consent form. If you sign this consent form, you are giving us permission to collect, use and share your health information. This permission is called authorization. If you do not want to provide authorization, then you cannot participate in this research study.

Who else will see your information?
Study records that identify you will be kept private. You will not be identified in study records or publications disclosed outside Northwell Health, except as detailed below.

Investigators will share information collected from this research study with:

- study sponsor and/or its agents,
- other researchers,
- accrediting agencies,
- data safety monitoring board,
- clinical staff not involved in the study who may be involved in participant's treatment,
- health insurers or payers
- Vitaltech
- Investigators from Cold Spring Harbor Laboratories, who are collaborators on this project.

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The following reviewers may access your study and medical records to make sure that this study is being done properly:

- Representatives from federal and state government oversight agencies such as the Food and Drug Administration, and/or the United States Department of Health and Human Services.
- Representatives from Northwell Health's Human Research Protection Program (the group of people that oversee research at this institution)

We will do our best to protect the privacy of your records but it is possible that once information is shared with people listed on this form, it may be released to others. If this happens, your information may no longer be protected by the federal law.

In the future, we may publish results of this study in scientific journals and may present it at scientific meetings. If we do we will not identify you.

If the researchers learn about potential serious harm to you or someone else or other public health concerns, it will be shared with the appropriate authorities.

Will you be able to access your records?
If your research records are used for decisions related to your clinical care, then you have the right to review this information and request changes. This is limited to information about your treatment, and does not include information related to procedures or tests that are for research purposes only. You may access this information only after the study analysis is complete. You have the right to know who has and who will see your records. To request this information, please call the Human Research Protection Program at 516-465-1910.

How long will your health information be kept?
There is no limit on the length of time we will keep your information for this research because it may be analyzed for many years. We will keep it as long as it is useful, unless you decide you no longer want to take part or we close the study. You are allowing access to this information indefinitely.

Who owns the data collected?
This information will not be owned by Vitaltech, the company we are using to collect the data. Your data (once de-identified) may be used for this study, but it cannot be traced back to you. Only the study investigators will have access to your data.

Can you change your mind?
If you change your mind about being in the study, you may withdraw from the study and thereby all activities related to it at any time. If you wish to stop taking the study drug, it would still help the research about COVID-19 if you continued filling out the daily questionnaire including the measurements of your body temperature, weight, oxygen saturation and lung function. In that case, please notify us that you will discontinue taking the study drug. If you want us to stop collecting your health information, you need to send a letter to the researcher at the following address:

Dr. Tobias Janowitz
Northwell Health- Office of Clinical Research
1981 Marcus Avenue, Suite E110
Lake Success, NY 11042

Your letter needs to say that you have changed your mind and do not want the researcher to collect and share your health information. You may also need to leave the research study if we cannot collect any more health information. We may still use the information we have already collected. We need to know what happens to everyone who starts a research study, not just those people who stay in it.

Will information about this study be available to the public?

A description of this clinical trial will be available on http://www.Clinical Trials.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 website at any time.

Will my information be used for research in the future?
Information or specimens collected from you for this research may be used for future research studies or shared with other researchers for future research. If this happens, information which could identify you will be removed before any information or specimens are shared. Since identifying information will be removed, there will not be an additional consent for future research. By consenting to participate in this study you are agreeing to allow your de-identified specimens and/or data to be used by future researchers without additional consent.

Does the investigator of this study receive money if you take part?
The investigators on this study do not receive money for your participation in this study.

Who can answer your questions about this study?
If you have any questions about the study, you may call The Office of Clinical Research at (516) 881-7067. If you have questions about side effects or injury caused by research you should call (516) 881-7067 or email clinicaltrials@northwell.edu. If you need emergency care, dial 911 or go to the nearest Emergency Room. If you have questions about your rights as a research participant, or concerns about being in the study, or would like to offer input, you may contact the Office of the Institutional Review Board (the committee that oversees research at this institution) at (516) 465-1910. A signed copy of this consent form will be given to you.

[Signature Page Follows]

Summation/Signature

You have read the above description of the research study. You have been told of the risks and benefits involved and all your questions have been answered to your satisfaction. A member of the research team will answer any future questions you may have. You voluntarily agree to join this study and know that you can withdraw from the study at any time without penalty. By signing this form, you have not given up any of your legal rights.

_____ _____

Signature of Participant Date

_____

Printed Name of Participant

_____

Printed Name of Witness

_____ _____

Signature of Witness Date

(Note: A witness can be a member of the research team, but cannot be the same person signing consent as the investigator)

Investigator's Statement

In addition to advising the above participant of other forms of treatment and therapy which are appropriate, I have offered an opportunity for further explanation of the risks and discomforts which are, or may be associated with this study and to answer any further questions relating to it.

_____ _____

Investigator's Signature **Date**

_____

Investigator's Printed Name