DUKE UNIVERSITY HEALTH SYSTEM

Consent to Participate in a Research Study
ADULT
Phase 2 Pragmatic Trial of Hydroxychloroquine, Azithromycin, or both for treatment of SARS-CoV-2 Infection

CONCISE SUMMARY
Coronavirus Disease 19 (COVID19) has emerged as a global pandemic, with hospitalization and mortality rates far exceeding that of the seasonal influenza viruses. At the present time, no targeted medications exist for treatment of COVID19. Potentially reusing already existing medications approved for use in other conditions, such as Hydroxychloroquine and/or Azithromycin, may benefit patients with this infection. Note that these study drugs are not approved for COVID19.

By your participation in this study, we hope to assess whether treatment with 5 days of Hydroxychloroquine alone, 5 days of Azithromycin alone, or 5 days of a combination of Hydroxychloroquine and Azithromycin, have an effect on COVID19.

There are some risks to these study drugs that are described in this document. Some of these risks include diarrhea, nausea/vomiting, visual changes, etc.

If you are interested in learning more about this study, please continue reading below.

You are being asked to take part in this research study because you have infection with SARS-CoV-2 virus causing Coronavirus Disease 19 (COVID19). Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below. If you are a caregiver, the terms "You" and "Your" refer to the patients for whom you are making decisions.

Your decision about participation in this study will have no effect on the regular care you will receive at Duke.

Please tell the study doctor or study staff if you are taking part in another research study.

Dr. Jason Stout will conduct the study and it is funded by Duke University.

WHO WILL BE MY DOCTOR ON THIS STUDY?
If you decide to participate, Dr. Jason Stout will be your doctor for the study and will be in contact with your regular health care provider throughout the time that you are in the study and afterwards, if needed.

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WHY IS THIS STUDY BEING DONE?
The SARS-CoV-2 virus can cause serious disease or death in some people who become infected. There are no treatments that are proven to help people infected with the virus at this time. This study will test two medicines that are currently available to treat other conditions, azithromycin and hydroxychloroquine, to see if they might help people who are infected with this virus. These medicines have been approved by the U.S. Food and Drug Administration (FDA) for many years, but not for the treatment of COVID. Therefore, these medicines are considered investigational drugs as used in this study. The word "investigational" means the study drug is still being tested in research studies and is not approved by the U.S. Food and Drug Administration (FDA) to treat COVID-19.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
Approximately 500 people will take part in this study at Duke University Hospital, Duke Regional Hospital, Duke Raleigh Hospital, the Durham Veterans Affairs Medical Center, among other medical centers nationwide.

WHAT IS INVOLVED IN THE STUDY?
If you agree to be in this study, you will be asked to sign and date this consent form. Your medical records will then be reviewed to make sure that you are eligible to participate in the study. There are 4 arms in this research study. You will be randomly assigned (like drawing numbers from a hat) to 1 of the 4 arms. You will have about a 3 out of 4 chance of receiving at least 1 study drug. The arms are:

1) 5 days of hydroxychloroquine alone
2) 5 days of azithromycin alone
3) 5 days of hydroxychloroquine + azithromycin
4) 5 days of no study drug.

Patients in all 4 arms will receive supportive care throughout the study. At present, there is no effective drug to treat COVID-19. If you are assigned to arm 4, you will receive the same care as if you were not in this study.

HOW LONG WILL I BE IN THIS STUDY?
You will be in the study for 28 days or for the rest of the time that you are in the hospital, whichever is longer.

You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled. However, if you decide to stop participating in the study, we encourage you to talk to your doctor first.

Clinically relevant results of this research will be communicated with you after conclusion of the study, analysis of the data, and publication of the results.

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WHAT ARE THE RISKS OF THE STUDY?
As a result of your participation in this study, you are at risk for the following side effects. You should discuss these with the study doctor and your regular health care provider if you choose.

Hydroxychloroquine may cause some, all or none of the side-effects listed below.

More likely
- Visual changes (blurred vision, color changes) – but usually with long term use

Less Likely
- Stomach pain
- Nausea
- Diarrhea
- Dizziness
- Headache
- Nervousness
- Nightmares
- Suicidal thoughts
- Muscle weakness
- Hearing loss
- Allergic reaction
- Skin rash
- Abnormal liver test / liver injury
- Abnormal heartbeat

Reproductive Risks
- The effects of maternal COVID-19 infection on a developing pregnancy or breastfeeding infant are not known. It is also not known if pregnancy or breastfeeding affect the outcomes of maternal COVID-19 infection. Hydroxychloroquine is routinely used during pregnancy and lactation as treatment for autoimmune disease with no evidence of any adverse effects.

Azithromycin may cause some, all or none of the side-effects listed below.

More likely
- Stomach pain
- Nausea
- Diarrhea

Less Likely

- Headache
- Dizziness
- Allergic reaction
- Skin rash
- Change in hearing
- Abnormal heartbeat
- Abnormal liver test / liver injury

For Those of Reproductive Potential

- Azithromycin is generally considered safe in pregnancy.

Drug and Food Interactions: For your safety, you must tell the study doctor or nurse about all the prescribed medical foods and drugs, herbal products, over-the-counter (OTC) drugs, vitamins, natural remedies, and alcohol that you are taking before you start the study and before starting to take any of these products while you are on the study.

There may be risks, discomforts, drug interactions or side effects that are not yet known.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?
If you agree to take part in this study, there may be direct medical benefit to you if you are placed in a study arm receiving either or both drugs. Receiving a study drug may improve the course of your illness with COVID19, including: preventing death, preventing or decreasing the need (number of days) for mechanical ventilation, decreasing the number of days in the hospital, and/or decreasing the severity or number of days of symptoms. We hope that in the future the information learned from this study will benefit other people with COVID19. If you are placed in arm 4 (no drug), it is not expected that you will receive direct benefit from being in the study since it is the same care you would receive if you were not participating.

WHAT ARE MY ALTERNATIVES TO PARTICIPATING IN THIS STUDY?
You can choose not to participate, and you will continue to receive Duke's usual care. Also, there may be other COVID studies for which you are eligible. Please talk to your study doctor about these other studies.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?
Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum

necessary information in order to conduct the research. Your personal information may also be given out if required by law. Your records may be reviewed in order to meet federal or state regulations. Reviewers may include representatives from the Food and Drug Administration, and the Duke University Health System Institutional Review Board, and others as appropriate. If any of these groups review your research record, they may also need to review your entire medical record.

The study results will be retained in your research record for at least six years after the study is completed. At that time either the research information not already in your medical record may be destroyed or information identifying you will be removed from such study results at DUHS. Any research information in your medical record will be kept indefinitely.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your name or other personal information will not be revealed.

Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS, we cannot guarantee that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

WHAT ARE THE COSTS TO YOU?
You or your insurance provider will be responsible and billed for all costs related to your routine medical care, including copayments and deductibles. Routine medical care services are those that you would have received for your condition if you were not participating in this research study. Not all services are covered by insurance. Some procedures or scans may require pre-authorization by your insurance plan. We will notify you if we learn that a service is not covered by your insurance plan as part of the pre-authorization process. If it is not covered, you will be responsible for paying for it. The amount of your out-of-pocket expense will depend on your insurance plan. For beneficiaries with Medicare Advantage Plans, traditional Medicare is billed for the routine cost of a research study. You may have more or higher co-pays than with a Medicare Advantage plan. Please discuss the costs of the study with Dr. Jason Stout. At your request, a Financial Counselor in the clinic may provide you with an estimate of costs for routine services.

We will monitor your DUHS patient care charges to make sure that costs are directed appropriately. If you have any questions or concerns about appropriate billing, contact your study team coordinator so that he/she can help find a resolution.

Please note: Taking part in this study may cost you and/or your insurance company more than the cost of getting regular medical treatment. The additional costs would include the cost of the study drugs hydroxychloroquine or azithromycin.

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WHAT ABOUT COMPENSATION?
You will not be reimbursed for your expenses related to your participation (parking, gas, and time).

WHAT ABOUT RESEARCH RELATED INJURIES?
Immediate necessary medical care is available at Duke University Medical Center in the event that you are injured as a result of your participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your Duke physicians to provide monetary compensation or free medical care to you in the event of a study-related injury.

For questions about the study or research-related injury, contact Dr. Jason Stout at 919-668-0826 during regular business hours and at 919-684-8111 after hours and on weekends and holidays and ask to have Dr. Stout paged.

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?
You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes unless the data concern an adverse event (a bad effect) related to the study. If such an adverse event occurs, we may need to review your entire medical record.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Duke. If you do decide to withdraw, we ask that you contact Dr. Jason Stout in writing and let him know that you are withdrawing from the study. His mailing address is Box 102359-DUMC, Durham, NC 27710.
We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

Your doctor may decide to take you off this study if your condition gets worse, if you have serious side effects, or if your study doctor determines that it is no longer in your best interest to continue. If this occurs, you will be notified and your study doctor will discuss other options with you.

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Biological Samples/Specimens
As part of your regular medical treatment (not as part of this study), blood samples will be drawn. From those samples, for this study, we would like to collect left over blood. If you would like to allow us to keep your leftover blood, you will be asked to sign a separate consent form titled "Duke Shared Data and Specimen Repository Regarding COVID-19 Patients." If you agree to allow your blood to be kept for future research with identifying information that could link your sample to you, you are free to change your mind at any time.

Study registered on the web site ClinicalTrials.gov
A description of this clinical trial will be available on https://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.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact Dr. Jason Stout at 919-668-0826 during regular business hours and at 919-684-8111 after hours and on weekends and holidays.

For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

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STATEMENT OF CONSENT
"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

_____ _____ _____
Signature of Subject Date Time

_____ _____ _____
Signature of Person Obtaining Consent Date Time

"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed copy of this consent form."

“I am the representative of the subject and am acting on behalf of the subject. I am not aware of any factor that might create a conflicting interest for me in this role (for example, something that might bring me personal benefit). I consent to the subject's participation in this study.

_____ _____ _____
Signature of Legal Representative Date Time

_____
Relationship to Subject

_____ _____ _____
Signature of Person Obtaining Consent Date Time