

The University of New Mexico Health Sciences Center
Consent and Authorization to Participate in a Research Study
Key Information for Treatment of Coronavirus SARS-Cov2 Respiratory Infections
with Hydroxychloroquine and Azithromycin.

You are being invited to take part in a research study about using hydroxychloroquine and azithromycin to treat respiratory infections caused by Coronavirus SARS-Cov2 (also called COVID-19).

WHAT IS THE PURPOSE, PROCEDURES, AND DURATION OF THE STUDY?

By doing this study, we hope to learn if these two drugs can help treat respiratory infections caused by Coronavirus SARS-Cov2. Your participation in this research will last about 14 days.

The purpose of this research is to gather information on the safety and effectiveness of hydroxychloroquine and azithromycin for the treatment of respiratory infections caused by Coronavirus SARS-Cov2. These two drugs are approved by the FDA for other conditions, but not for respiratory infections caused by Coronavirus SARS-Cov2. There are currently no drugs approved by the FDA for this condition.

WHAT ARE THE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

You may want to participate in this study because the drugs may help treat your current respiratory infection. You may also want to participate in order to help find a treatment for this condition. For a complete description of benefits, refer to the Detailed Consent.

WHAT ARE THE KEY REASONS YOU MIGHT NOT CHOOSE TO VOLUNTEER FOR THIS STUDY?

You might choose not to volunteer for this study because the drugs may not help treat your respiratory infection, or because you might lose privacy and/or confidentiality. For a complete description of the risks, refer to the Detailed Consent and to the Appendix.

Alternate treatments or procedures would include having access to the study medications without taking part in this study. There is currently no standard of care treatment for treating the viral infection.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of this study is Dr. Cristina Beato of the University of New Mexico Health Sciences Center, Department of Family Medicine. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study, her contact information is (505) 272-5066.

If you have any questions or concerns about your rights as a volunteer in this research, contact staff in the University of New Mexico Health Sciences (UNMHSC) Human Research Review Committee (HRRC) between the business hours of 8AM and 5PM, Mountain Standard Time (MST), Monday-Friday at 505-272-1129.

DETAILED CONSENT

Version April 27, 2020

ARE THERE REASONS WHY YOU WOULD NOT QUALIFY FOR THIS STUDY?

You would not qualify to be in this study for the following reasons:

- You are under the age of 18 or older than 74.
- You are transferred from an intensive care unit from an external entity regardless of age.
- You are transferred from a nursing home regardless of age.
- You are pregnant or breastfeeding.
 - There is insufficient information regarding the safety of azithromycin during pregnancy. Consequently, Azithromycin is not recommended when pregnant or planning to become pregnant. However, investigators may prescribe it if necessary.
 - Azithromycin is excreted in human milk, therefore participants should not breast-feed while taking Azithromycin, because it may cause side effects including diarrhea and infection in your baby. It is recommended to discard the milk during treatment and up until 2 days after discontinuation of treatment. However, investigators may prescribe it if necessary.
 - Hydroxychloroquine is not recommended during pregnancy. However, investigators may prescribe it if necessary.
 - hydroxychloroquine is not recommended if you are breast-feeding or planning to breast-feed. This is because small amounts may pass into mother's milk. However, investigators may prescribe it if necessary.
- You have an allergy to one of the study drugs or have contraindication to treatment with study drugs.
- You have retinopathy.
- You have Glucose-6-phosphate dehydrogenase (G6PD) deficiency.
- You have QT prolongation. Unless, it is the opinion of the treating physicians that the benefits to treat with the medications outweigh the risks.
- You have known chronic kidney disease or are receiving dialysis.
- You have a weight of less than 40 kg.
- You are currently using hydrochloroquine.
- You are currently using cardiac medicines as follows: flecainide, Tambocor; amiodarone Cordarone, Pacerone; digoxin or Digox, Digitek, Lanoxin; procainamide or Procan, Procanbid, propafenone, Rythmal.

WHERE IS THE STUDY GOING TO TAKE PLACE AND HOW LONG WILL IT LAST?

The research procedures will be conducted at University of New Mexico Hospital while you are hospitalized. The total amount of time you will be asked to volunteer for this study is over the next 14 days.

WHAT WILL YOU BE ASKED TO DO?

If you agree to participate in this study, you will take two drugs:

1. Hydroxychloroquine (2 times per day for 7 days)
2. Azithromycin (1 time per day for 5 days)

These drugs will be given by mouth, but may be given through a feeding tube (if the patient) has one and/or through an IV (tube in a vein) if necessary.

We will collect the research specimen using a deep nose swab on day 3, 6 and 14. If necessary, a swab may be used in the trachea (windpipe) to collect the sample.

You will still receive all the other treatments, test and procedures you would get if you did not participate in this study. We will look into your medical record (chart) to get the information recorded to use in the study.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS

If you participate in this study, there is a risk of cardiomyopathy, retinopathy, hepatic failure, and/or suicidal ideation. There is always a chance that any medical treatment can harm you. The research treatments/procedures in this study are no different. For a complete description of the risks, refer to the Appendix. In addition to risks described in this consent, you may experience a previously unknown risk or side effect.

WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?

We do not know if you will get any benefit from participating in this study. However, some people have experienced having less of the virus in their respiratory secretions when taking these two drugs. If you take part in this study, information learned also may help others with your condition.

WHAT WILL IT COST YOU TO PARTICIPATE?

You and/or your insurance company, Medicare, or Medicaid will be responsible for the costs of all care and treatment that you would normally receive for any conditions you may have. These are costs that are considered medically necessary and will be part of the care you receive even if you do not take part in this study.

The University of New Mexico may not be allowed to bill your insurance company, Medicare, or Medicaid for the medical procedures done strictly for research. This means you may have to pay out-of-pocket for these costs.

If a health insurance company insures you, your insurer may pay the costs. You should ask your insurer if you have any questions regarding your insurer's willingness to pay these costs.

If Medicare or Medicaid covers you, Medicare or Medicaid may cover these costs. For questions regarding Medicare coverage, call 1-800-MEDICARE (1-800-633-4227). For questions regarding Medicaid coverage, call 1-800-2570. Your insurer, Medicare, or Medicaid, may agree to pay for the costs. If you are required to expend a co-payment or deductible, the amount of this co-payment or deductible may be costly.

WHO WILL SEE THE INFORMATION THAT YOU GIVE

Each person participating in this Study will be assigned a randomly generated study ID that will be linked to identifiers (MRN, DOB) in a linking table to be kept separate from the research data. Data and specimens will be labelled with the study ID only. Only HRRC-approved members of the study team who have the appropriate training will have access to the data and identifiers. All data that we collect in this study will be entered into REDCap, a secure data-base, on a password-protected computer using a secure network. Any hard copy records/data will be kept in a locked file cabinet in the locked office of a designated member of the Study team. The specimens will be kept and stored in the Clinical and Translational Science Center at the UNM HSC and can only be accessed by the members of the study

team. We will transport the specimens to TriCore Reference Laboratories for lab analysis through standard transport hospital procedures. After testing, any left-over samples will be delivered in part to CDC for validation testing, and in part to the CTSC for genomic sequencing. Once data collection is complete, data will be de-identified by destruction of the linking table. Study records will be kept for 6 years past study closure.

When we write about or share the results from the study, we will write about the combined information. We will keep your name and other identifying information private.

We will make every effort to prevent anyone who is not on the research team from knowing that you gave information, or what the information is.

You should know there are some circumstances in which we may have to show your information to other people. For example, the law may require us to share your information with the following agencies and for the following reasons:

- The law requires us to share your information with authorities if you report information about a child being abused
- If you pose a danger to yourself or someone else.
- A court or agencies, if you have a reportable disease or condition.
- Authorities, if you report information about a child being abused, if you pose a danger to yourself or someone else.

CAN YOU CHOOSE TO WITHDRAW FROM THE STUDY EARLY?

You can choose to leave the study at any time. You will not be treated differently if you decide to stop taking part in the study.

If you choose to leave the study early, data collected until that point will remain in the study database and may not be removed.

The investigators conducting the study may need to remove you from the study. The study intervention, medication will no longer be provided to you and may not be available for purchase. This may occur for a number of reasons. You may be removed from the study if you are not able to follow the direction, they find that your participation in the study is more risk than benefit to you, or if Dr. Beato chooses to stop the study early for a number of scientific reasons.

You may be removed from the study if:

- You are not able to follow the directions.
- They find that your participation in the study is more risk than benefit to you.

ARE YOU PARTICIPATING, OR CAN YOU PARTICIPATE, IN ANOTHER RESEARCH STUDY AT THE SAME TIME AS PARTICIPATING IN THIS ONE?

You may not take part in this study if you are currently involved in another research study. It is important to let the investigator and your doctor know if you are in another research study. It will be up to them to determine if you can participate in more than one study. You should discuss this with the investigator and your doctor before you agree to participate in another research study while you are in this study.

WHAT HAPPENS IF YOU GET HURT OR SICK DURING THE STUDY?

If you believe you are hurt or if you get sick because of something that is due to the study, you should call Dr. Cristina Beato at (505) 272-5066 immediately. If you need to reach someone outside of business hours, please call (505) 272-2121.

Dr. Beato will determine what type of treatment, if any, is best for you at that time.

It is important for you to understand that the University of New Mexico does not have funds set aside to pay for the cost of any care or treatment that might be necessary because you get hurt or sick while taking part in this study. Also, the University of New Mexico will not pay for any wages you may lose if you are harmed by this study.

Medical costs related to your care and treatment because of study-related harm will be paid by you and/or your insurance

WILL I BE PAID FOR PARTICIPATING IN THIS STUDY?

You will not receive any rewards or payment for taking part in the study.

WHAT IF NEW INFORMATION IS LEARNED DURING THE STUDY THAT MIGHT AFFECT YOUR DECISION TO PARTICIPATE?

You will be informed if the investigators learn new information that could change your mind about staying in the study. You may be asked to sign a new informed consent form if the information is provided to you after you have joined the study.

WILL YOU BE GIVEN INDIVIDUAL RESULTS FROM THE RESEARCH TESTS?

You and your doctor will be given individual results from the research tests.

A member of the study team will contact you using the information you provided. With the help of a member of the study team, they will present possible risks or benefits of receiving the information. At that time you can choose to receive or refuse the result or finding. If you would like more information about this, please call Dr. Beato.

You may also withdraw your consent to be contacted with information about research results by sending a written request to Dr. Beato.

A description of this clinical trial will be available on [ClinicalTrials.gov](https://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 website at any time.

WHAT ELSE DO YOU NEED TO KNOW?

If you volunteer to take part in this study, you will be one of up to 10,000 people to do so.

FUTURE USE OF YOUR INFORMATION OR PROTECTED HEALTH INFORMATION

Identifiable information such as your name, medical record number, or date of birth will be removed from the information or samples collected in this study. After removal, the information or samples may be used for future research or shared with other researchers without your additional informed consent.

In addition to the main study, you are being asked to allow us to keep and use your information for future research.

HIPAA AUTHORIZATION FOR USE AND DISCLOSURE OF YOUR PROTECTED HEALTH INFORMATION (PHI).

As part of this study, we will be collecting health information about you and sharing it with others. This information is “protected” because it is identifiable or “linked” to you.

Protected Health Information (PHI)

By signing this Consent Document, as described in this consent form, you are allowing the investigators and other authorized personnel to use your protected health information for the purposes of this study. This information includes results of tests and exams done for your clinical care, your medical history, and other information related to the treatment of your condition.

In addition to researchers and staff at UNMHS and other groups listed in this form, there is a chance that your health information may be shared (re-disclosed) outside of the research study and no longer be protected by federal privacy laws. Examples of this include health oversight activities and public health measures, safety, monitors, other sites in the study, companies that sponsor this study, government agencies such as Food and Drug Administration (FDA).

Right to Withdraw Your Authorization

Your authorization for the use and disclosure of your health information for this study shall not expire unless you cancel this authorization. This is because the information used and created during the study may be analyzed for many years and it is not possible to know when this will be complete. Your health information will be used or disclosed as long as it is needed for this study. However, you may withdraw your authorization at any time provided you notify the UNM investigators in writing. To do this, please send letter notifying them of your withdrawal to:

Cristina Beato, MD
MSC 09 5040
1 University of New Mexico
Albuquerque New Mexico 87131

Please be aware that the research team will not be required to destroy or retrieve any of your health information that has already been used or shared before the date that your withdrawal is received.

If you become pregnant anytime during the study or within 15 days after stopping the study drug, you must inform the study doctor. The study doctor must then report the outcome of your pregnancy to the Sponsor (and/or the FDA).

The researchers agree to only share your health information with the people listed in this document. Should your health information be released to anyone that is not regulated by the privacy law, your health information may be shared with others without your permission; however, the use of your health information would still be regulated by applicable federal and state laws.

You may not be allowed to participate in the research study if you do not sign this form. If you decide not to sign this form it will not affect your:

- Current or future healthcare at the University of New Mexico;
- Current or future payments to the University of New Mexico;
- Ability to enroll in any health plans (if applicable); or
- Eligibility for benefits (if applicable).

After signing the form, you can change your mind and NOT let the researcher(s) collect or release your health information (revoke the Authorization). If you revoke the authorization:

- You will send a written letter to Dr. Beato to inform her of your decision.
- Researchers may use and release your health information already collected for his research study.
- Your protected health information may still be used and released should you have a bad reaction (adverse event).

The use and sharing of your information has no time limit.

If you have not already received a copy of the Privacy Notice, you may request one. If you have any questions about your privacy rights, you should contact the University of New Mexico Health Sciences Privacy Officer between the business hours of 8am and 5pm Mountain Pacific Time, Monday-Friday at (505) 272-1493.

INFORMED CONSENT SIGNATURE PAGE

You are participating or are authorized to act on behalf of the participant. This consent includes the following:

- Key Information Page
- Detailed Consent

You will receive a copy of this consent form after it has been signed.

Signature of research subject, or if applicable,
**research subject's legal representative*

Date

Printed name of research subject

**If applicable, printed name of research subject's legal representative*

*If applicable, please explain Representative's relationship to subject and include a description of representative's authority to act on behalf of subject.

I have witnessed the informed consent process. This informed consent form was verbally reviewed with the subject or their LAR in addition to the HRRC approved short consent form and will act as the written summary of the discussion.

Witness (translator) printed name

Witness (translator) signature and date

I have witnessed the informed consent process that was conducted by phone call or by conference phone call. This informed consent form was verbally reviewed with the subject or their LAR.

Impartial Witness to phone consent printed name

Impartial Witness to phone consent signature and date

Adult Assent (if applicable)

You are making a decision whether to participate in this study. Your signature below indicates that you read the information provided (or the information was read to you).

Name of Adult Participant

Date

Signature of Adult Participant

Printed name of [authorized] person obtaining
informed consent/HIPAA Authorization

Date

Signature of [authorized] person obtaining
informed consent/HIPAA Authorization

Appendix 1: Risks

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS OF AZITHROMYCIN?

Like all medicines, Azithromycin can cause side effects, although not everybody gets them.

Tell your doctor and the study doctor, Dr. Beato, immediately if you experience any of the following symptoms after taking this medicine as the symptoms may be severe- you may need urgent medical treatment:

- difficulty breathing, sudden wheeziness, swelling of the eyelids, face or lips, rash or itching (especially affecting the whole body)
- severe or prolonged diarrhea, which may have blood or mucus in it during or after treatment with Azithromycin as this may be a sign of serious bowel inflammation
- severe skin rash causing redness and flaking
- rapid or irregular heartbeat
- low blood pressure
- serious skin reactions:
 - blistering of the skin, mouth, eyes and genitals (Stevens-Johnson Syndrome (SJS))
 - blistering of the skin, severe skin reaction (Toxic Epidermal Necrosis (TEN))
 - skin rash accompanied by other symptoms such as fever, swollen glands and an increase of eosinophils (a type of white blood cell). A rash appears as small, itchy red bumps (Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS))
 - skin eruption that is characterized by the rapid appearance of areas of red skin studded with small pustules (small blisters filled with white/yellow fluid) (Acute Generalized Exanthematous Pustulosis (AGEP) – rare (may affect 1-10 users in 10,000))

The most common side effects that occur when taking Azithromycin are listed below. These may go away during treatment as your body adjusts to the medicine. Tell your doctor and Dr. Beato if any of these side effects continue to bother you.

Other side effects include:

Very common (affects more than 1 user in 10)

- diarrhea, stomach cramps, feeling sick, wind

Common (affects 1 to 10 users in 100)

- headache, dizziness
- being sick (vomiting), indigestion
- low number of lymphocytes (a type of white blood cells), higher number of eosinophils (a type of white blood cell)
- low blood bicarbonate

- numbness or pins and needles
- loss of appetite, taste disturbance
- visual disturbances, deafness
- skin rash and /or itching
- joint pain
- tiredness or weakness

Uncommon (affects 1 to 10 users in 1,000)

- yeast infections of the mouth and vagina (thrush)
- low numbers of leukocytes (a type of white blood cell), low number of neutrophils (a type of white blood cell)
- allergic reactions of various severity
- skin more sensitive to sunlight than normal
- feeling nervous
- reduced sense of touch or sensation (hypoesthesia)
- sleepiness or sleeplessness (insomnia)
- poor hearing or ringing in the ears
- heart palpitations, chest pain
- constipation, stomach pain associated with diarrhea and fever
- inflammation of the liver (hepatitis), changes in liver enzymes
- general loss of strength
- swelling
- general discomfort
- abnormal laboratory test values (e.g. blood or liver tests)

Rare (affects 1 to 10 users in 10,000)

- feeling agitated
- changes in liver function
- vertigo

Not known (frequency cannot be estimated from the available data)

- fits or fainting
- aggression or anxiety
- feeling hyperactive
- localised muscle weakness
- loss of smell or altered sense of smell, loss of taste
- tongue discolouration
- inflammation of the pancreas (pancreatitis)
- inflammation of the kidney or kidney failure
- yellowing of the skin or eyes (jaundice) or liver failure (rarely life-threatening)
- bruising or prolonged bleeding after injury

- abnormal electrocardiogram (ECG)
- reduction in red blood cells which can make the skin pale and cause weakness or breathlessness

If any of the side effects gets serious, or if you get any side effects talk to your doctor and Dr. Beato. This includes any possible side effects not listed here.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS OF HYDROXYCHLOROQUINE?

Like all medicines, hydroxychloroquine can cause side effects, although not everybody gets them.

Tell your doctor and the study doctor, Dr. Beato, immediately if you experience any of the following symptoms after taking this medicine as the symptoms may be severe- you may need urgent medical treatment:

Not known (frequency cannot be estimated from available data)

- You have an **allergic reaction**. The signs may include: a red or lumpy rash, swallowing or breathing problems, swelling of the eyelids, lips, face, throat or tongue.
- Severe skin reactions such as blistering, widespread scaly skin, pus-filled spots together with a high temperature, reddening and being more sensitive to the sun.
- Blistering or peeling of the skin around the lips, eyes, mouth, nose and genitals, flu-like symptoms and fever. This could be a condition called Stevens-Johnson Syndrome.

Common side effects (may affect less than 1 in 10 people)

- You have any eye problems. This includes changes in the colour of your eye and problems with your eyesight such as blurring, sensitivity to light or the way you see colour.

Uncommon side effects (may affect less than 1 in 100 people)

- You have any muscle weakness, cramps, stiffness or spasms or changes in sensation such as tingling. If you take this medicine for a long time, your doctor will occasionally check your muscles and tendons to make sure they are working properly.

Not known (frequency cannot be estimated from available data)

- You have frequent infections such as fever, severe chills, sore throat or mouth ulcers. These could be signs of a blood problem called 'leucopenia' or 'agranulocytosis'.
- You may bruise more easily than usual. This could be due to a blood problem called 'thrombocytopenia'.
- You feel tired, faint or dizzy and have pale skin. These could be symptoms of something called 'anemia'.
- You feel weak, short of breath, bruise more easily than usual and get infections more easily than usual. These could be symptoms of something called 'aplastic anemia'.

- Weakening of the heart muscle (cardiomyopathy) resulting in difficulty breathing, coughing, high blood pressure, swelling, increased heart rate, low amount of urine.
- Low blood sugar levels (hypoglycaemia). You may feel a sense of nervousness, shaky or sweaty.
- You notice yellowing of your skin or your eyes or your urine becomes darker in colour.
- Fits.
- Lack of movement, stiffness, shaking or abnormal movements in the mouth and tongue.

Tell your doctor or pharmacist if any of the following side effects get serious or lasts longer than a few days:

Very common side effects (may affect more than 1 in 10 people)

- Stomach pain
- Feeling sick

Common side effects (may affect less than 1 in 10 people)

- Skin rashes, itching
- Being sick, diarrhea
- Loss of appetite (anorexia)
- Headache
- Changes in mood with uncontrollable laughing or crying

Uncommon side effects (may affect less than 1 in 100 people)

- Changes in the colour of your skin or the inside of your nose or mouth
- Hair loss or loss of hair colour
- Feeling nervous
- Ringing in the ear (tinnitus)
- Balance problems (vertigo) or feeling dizzy
- Liver problems shown by blood tests

Not known (frequency cannot be estimated from available data)

- Psoriasis (red scaly patches on the skin usually affecting the knees, elbows and scalp)
- Hearing loss
- Mental problems (such as delusions, hallucinations and changes in mood)
- Symptoms of a condition called ‘porphyria’ which may include stomach pain, being sick, fits, blisters, itching

If any of the side effects gets serious, or if you get any side effects talk to your doctor and Dr. Beato. This includes any possible side effects not listed here.