California Human Research Participant's Bill of Rights

California Health and Safety Code §24172. The Experimental Research Subject's Bill of Rights is a list outlining your rights as a subject in a medical experiment.

Except as otherwise provided in §24172, this list shall include, but not be limited to, the subject's right to:

1. Be informed of the nature and purpose of the experiment.
2. Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be used.
3. Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment, if applicable.
4. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.
5. Be given a disclosure of any appropriate alternative procedures, drugs, or devices that might be advantageous to the subject, and their relative risks and benefits.
6. Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications arise.
7. Be given an opportunity to ask any questions concerning the experiment or the procedures involved.
8. Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation in the medical experiment without prejudice.
9. Be given a copy of the signed and dated written consent form.
10. Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.

By signing below, I acknowledge I have received a copy of this document

_____

Subject Name

_____ _____

Signature of Subject Date

E&I Review Services
IRB Study #20070
05/12/2021

RESEARCH SUBJECT CONSENT FORM AND HIPAA AUTHORIZATION

Title: A Randomized, Double-Blind, Placebo-Controlled Phase IIa Study of Hydroxychloroquine, Vitamin C, Vitamin D, and Zinc for the Prevention of COVID-19 Infection

Brief Title: HELP COVID-19

Protocol Number: ProgenaBiome 042

Sponsor: ProgenaBiome, LLC
1845 Knoll Drive
Ventura, CA 93003

Principal Investigator: Dr. Sabine Hazan, MD
Chief Operating Officer and Founder
ProgenaBiome, LLC
1845 Knoll Drive
Ventura, CA 93003
support@progenabiome.com

Sabine Hazan is CEO of ProgenaBiome, LLC

Site(s): ProgenaBiome, LLC
1845 Knoll Drive
Ventura, CA 93003

Study Related Phone Number: Daytime phone number: 805-339-0549
24-hour number: 800-920-0016

This consent form may contain words that you do not understand. Please ask the investigator to explain any words or information you do not understand. You may have an unsigned electronic copy of this form to take home in order to discuss with family members or friends before making your decision.

Participating in a research study is not the same as getting regular medical care. The purpose of regular medical care is to improve your health. The purpose of a research study is to gather information.

E&I Review Services
IRB Study #20070
05/12/2021

RESEARCH CONSENT SUMMARY

Introduction
You are being asked to take part in a research study. This document will tell you how the research will be conducted, what you will be asked to do if you decide to participate, and may help you make an informed decision whether you would like to take part. These details are provided in the sections below.

What should I know about this research?
The goal of this research study is to see if this combination of therapies can prevent infection with COVID-19. The combination of therapies being used in this study are hydroxychloroquine, with vitamin C, vitamin D, and zinc. Their use for the possible prevention of COVID-19 symptoms is experimental and has not been approved by the Food and Drug Administration (FDA).

What happens to me if I agree to take part in this research?
If you decide to take part in this research, after you are deemed eligible to participate, you will be randomly assigned to one of two groups. There will be a 50% chance of being in either group (like flipping a coin).

If you are assigned to the treatment group, you will be given hydroxychloroquine for one day, and vitamin C, vitamin D, and zinc, for the duration of the trial. You will be followed for a period of 12 weeks to monitor your health.

If you are assigned to the placebo group, you will be given a placebo for one day, and vitamin C, vitamin D, and zinc for the duration of the trial. You will be followed for a period of 12 weeks to monitor your health.

How long will I be in this research?
In total your participation in this study should take about 3 months.

Why is this research being done?
The purpose of this study is to determine whether using the study drug combination can prevent COVID-19.

What is a placebo?
A placebo is something that looks like a drug, but doesn't have the active substance inside. These are often referred to as "sugar pills", although they don't always contain any sugar.

Why are placebos used in research?
Using a placebo with some participants helps researchers to know if the active drug works better. Some participants are given a placebo, others are given the active drug, while both groups undergo the same testing, so that these equal groups can be compared with accuracy.



What is a double-blind study?
A double-blind study means neither the participant nor the investigator knows whether the participant is being given the active drug or the placebo.

Could being in this research hurt me?
There are potential side effects of the medications, which are listed below. Some medications may interact with the study medications in a bad way. One category of medications which can interact with the study drug is anti-epileptics. These drugs are not always prescribed for epilepsy, many of them have other uses. So we will discuss any medications or supplements you may be taking.

One side effect, low blood sugar (also known as hypoglycemia) is something you should watch out for. Signs of low blood sugar include irregular or fast heartbeat, fatigue, pale skin, shakiness, anxiety, sweating, hunger, irritability, and tingling or numbness of the lips, tongue, or cheek. If you feel you may be experiencing low blood sugar, please contact the study doctor right away.

Will being in this research benefit me?
If this research is effective, it could potentially prevent COVID-19. You will not benefit directly from this study if you are assigned to the placebo group or if the drug combination does not work.

What other choices do I have besides taking part in this research?
As there is no FDA-approved prophylaxis for COVID-19, any medications for preventing the infection are considered experimental. The drug combination being used in this study is experimental.
Your other choice is not to participate.

While there is no FDA approved prophylaxis against COVID-19, the FDA has granted Emergency Use Authorization for vaccines, which have shown to be effective against COVID-19 infection. Vaccination will protect most people from getting infected.

DETAILED RESEARCH CONSENT

Introduction

You are being asked to take part in a research study because you are a health care worker with possible exposure to COVID-19 or you may be living with or exposed to someone with a known positive COVID-19 test. A person who takes part in a research study is called a research subject or research participant.

Background Information

From what we have learned from treating this virus as well as other viruses, medications to treat viruses are more powerful and effective when used together. That is why we want to try preventing COVID-19 infection with a combination of drugs.

What should I know about this research?

- Someone will explain this research to you.
- This form sums up that explanation.
- Taking part in this research is voluntary. Whether you take part is up to you.
- You can choose not to take part. There will be no penalty or loss of benefits to which you are otherwise entitled.
- You can agree to take part and later change your mind. There will be no penalty or loss of benefits to which you are otherwise entitled.
- If you don't understand, ask questions.
- Ask all the questions you want before you decide.

Purpose of this research study

The goal of this research study is to see if this combination of therapies can prevent COVID-19 infection. The combination of therapies being used in this study are hydroxychloroquine, with vitamin C, vitamin D, and zinc. Their use for the possible prevention of COVID-19 symptoms is experimental and has not been approved by the FDA.

How long will I be in this research?

You will take hydroxychloroquine or a placebo for one day. You will take vitamin C, vitamin D, and zinc throughout the duration of the trial. The trial will end in 12 weeks.

Procedures

First you will be screened to determine if you are eligible to participate in the study. This will be done over the phone, and you will look at study documents online. You will need to let the study staff know if you have gotten or are planning to get the COVID-19 vaccine. You will provide consent via an on-line portal called an EDC or Electronic Data Capture system. You may take as much time as you need to complete this form.

You will also consent to have your medical records released to us so that we can get your health history. This will give us a baseline to compare to throughout the study.

E&I Review Services
IRB Study #20070
05/12/2021

You will provide a baseline EKG reading. This must be completed before any study medications can be provided.

If you have a history of G6PD deficiency you cannot participate in this trial. If you have any of the signs of this condition (rapid heart rate, shortness of breath, urine that is dark or yellow-orange, fever, fatigue, dizziness, paleness, jaundice, or yellowing of the skin and whites of the eyes) the investigator will order a blood test to check for this disorder. If you wish to be tested prior to taking study medications, you may request this from the investigator. If your insurance does not cover this cost, ProgenaBiome will pay for this test.

After we have determined that you are eligible for the study, you will be randomly assigned into either the treatment group or the placebo group. Neither you nor the investigator will know which group you are in. We will send you the study medications (either hydroxychloroquine or a placebo, vitamin C, vitamin D, and zinc), a daily diary, and a pregnancy test, if applicable. We will also send you swabs to collect samples for COVID-19 testing. These will be sent by rapid carrier.

On Day 1 of the study, you will be called in the morning to discuss the materials you have received and to be instructed in their use. We will discuss the medications, going over when and how much to take. We will go over the study diary and how to complete it in the EDC system. We will also answer any questions you may have. You must take the pregnancy test before taking any study medications (if applicable). If you are pregnant, you cannot take the study drugs. You will take your temperature, collect a nasal or oropharyngeal (back of the throat) swab for testing, then take the medications as directed, and complete the diary.

Day 2 you will take your temperature and take the study medications in the morning and the evening. You will be called to ask if you are experiencing any side effects or symptoms of COVID-19. You will complete your daily diary.

Days 3 through 7 you will take your temperature, complete the diary, and take the study medications in the morning and the evening as directed.

Weeks 2-12 you will be called weekly to update the list of any medications you are taking, discuss side effects and COVID-19 symptoms. You will take your temperature weekly, take the medications in the morning and the evening as directed, and complete the diary.

During Day 14 and Day 30, you will collect a nasal or oropharyngeal (back of the throat) swab for testing. We will call you on Day 14 to give you instructions on how to do this.

Week 12 you will have either an in-person visit to the clinic, or a videoconference. The videoconference will not be recorded and it may take 60 minutes. Please find a private and quiet place during the

videoconference. You will discuss any side effects you may have experienced, any medications you have taken, and if this visit takes place in the clinic you will undergo a physical exam. If this visit is in the clinic we will collect the final nasal or oropharyngeal (back of the throat) swab for testing, otherwise you will collect this.

If at any time during the study you become symptomatic for COVID-19, contact your primary care physician (PCP) to be tested. If this test is positive, you must stop taking the study medications. You will be treated by your PCP. We will continue to follow your health for the remainder of the study period.

If any time during the study, you experience a side effect, or other research-related injury or harm, contact the Principal Investigator listed on Page 2 to report it.

Participation in the ProgenaBiome, LLC Research Study will consist of:

1. Allowing access to your medical records, including a baseline EKG reading
2. Taking a pregnancy test (if applicable)
3. Taking study medications
4. Collecting nasal or oropharyngeal (back of the throat) swabs
5. Sharing personal information about yourself
6. Receiving follow-up phone calls from the clinic for evaluation
7. Follow-up visit to the clinic for evaluation

What are my responsibilities if I take part in this research?

- Please take the prescribed study medication as directed
- Please collect nasal or oropharyngeal (back of the throat) swabs
- Please complete the daily diary
- Please answer all follow-up calls
- Please attend follow-up visit
- Please ask questions if anything is unclear to you
- Please inform the study staff if you have any concerns

Security, Use, and Sharing of Data

Your personal information and medical records will be protected by ProgenaBiome, LLC with physical, technical, and administrative procedures. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

We will protect your information from disclosure to others to the extent required by law. We cannot promise complete confidentiality.

A description of this clinical trial will be available on http://www.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.



Deidentified data or specimens collected in this research might be used for future research or distributed to another investigator for future research without your consent.

Your information will be coded, and only specific personnel will have access to the code. In addition to individual analysis, your information will be pooled with that of other participants and analyzed as a group. These analyses and your information will be kept as confidential as possible. This is accomplished by storing your information in password-protected computers and physical copies in locked cabinets. This information will be stored indefinitely.

You may be contacted by ProgenaBiome, LLC in the future, if follow-up research requires additional information or specimen samples. It will be your choice whether or not to participate in this future research.

ProgenaBiome, LLC's internal researchers may collaborate with external members of our research group. These data will not contain any identifying information and will be pooled, with the following exceptions:

1. If ProgenaBiome, LLC asks for and receives your explicit authorization ProgenaBiome, LLC may release your individual data to a third party.
2. ProgenaBiome, LLC, if requested by law enforcement agencies, country of law, regulatory and government agencies, or are otherwise required by law to do so, may release your individual-level information.
3. The Institutional Review Board (IRB), the Food and Drug Administration and other government agencies responsible for monitoring our Research Study may inspect the research records. All of the representatives from outside groups are obligated to keep the information you provide confidential.
4. With your permission, ProgenaBiome, LLC's may allow researchers to have access to data with your name and contact information removed.

Benefits

Your participation in this study may or may not prevent you from getting symptoms of COVID-19 infection. If you are placed in the placebo group or if the drug combination does not work, there will be no direct benefit to you. Either way, we will learn new information about this drug combination.

Risks

Some potential risks:

- You or family members may be uncomfortable with some of the health questions.
- There are specific medications you may not take during the study. We will discuss these medications with you, and they are listed on pages 12-14. We will discuss with you what medications and/or supplements you may be taking to make sure that you aren't taking anything on this list.
- You may experience side effects from the medication, including serious side effects



- Risks associated with Hydroxychloroquine
  - a. Auditory
    - i. Tinnitus
    - ii. Hearing loss
  - b. Cardiovascular
    - i. Cardiomyopathy (can result in fatal cardiac failure)
    - ii. biventricular hypertrophy
    - iii. Prolongation of Q-T Interval
  - c. Dermatologic
    - i. Pigmentary changes in skin and mucous membranes
      1. Usually reversible upon discontinuation of medication
    - ii. Bleaching of hair
      1. Usually reversible upon discontinuation of medication
    - iii. Alopecia
      1. Usually reversible upon discontinuation of medication
    - iv. Rash/pruritus
    - v. AGEP
      1. Usually reversible upon discontinuation of medication
    - vi. Outbreak of psoriasis, occasionally associated with fever and hyperleukocytosis
    - vii. Urticaria
    - viii. Angioedema
    - ix. Bullous eruptions including
      1. Erythema multiforme
      2. Stevens-Johnson syndrome
      3. Toxic epidermal necrolysis
    - x. DRESS syndrome
    - xi. Photosensitivity
    - xii. Exfoliative dermatitis
  - d. Gastrointestinal
    - i. Abdominal pain
    - ii. Nausea
    - iii. Diarrhea
    - iv. Vomiting
  - e. Hematologic
    - i. Bone marrow suppression
    - ii. Anemia
    - iii. Aplastic anemia
    - iv. Agranulocytosis
    - v. Leukopenia
    - vi. Thrombocytopenia
  - f. Hepatic
    - i. Fulminant hepatic failure
  - g. Metabolic
    - i. Anorexia
    - ii. Hypoglycemia
    - iii. Exacerbation or precipitation of porphyria
  - h. Musculoskeletal
    - i. Sensorimotor dysfunction
    - ii. Skeletal muscle myopathy or neuromyopathy
      1. May be reversible by stopping medication but recovery could take months
    - iii. Depression of tendon reflexes
    - iv. Abnormal nerve conduction studies
  - i. Nervous system
    - i. Headache
    - ii. Dizziness
    - iii. Seizure
    - iv. Vertigo
    - v. Auditory nerve dysfunction
    - vi. Ataxia
  - j. Optical
    - i. Blurred vision
      1. Dose dependent and reversible upon discontinuation of medication
    - ii. Retinopathy with changes in pigmentation and other visual field defects
      1. Participants with retinal changes may be asymptomatic initially, or may have scotomatous vision with paracentral, pericentral ring types, temporal scotomas, and abnormal color vision.
    - iii. Corneal changes including edema and opacities can be symptomless or may cause disturbances such as haloes, blurring of vision, or photophobia. They may be transient and are reversible when therapy is discontinued.
    - iv. Maculopathies and macular degeneration (may be irreversible), extra-ocular muscle palsies (reversible), nystagmus
      1. Maculopathies, and macular degeneration, can occur from 3 months to several years of exposure to this drug and may be irreversible
  - k. Psychiatric
    - i. Affect lability
    - ii. Nervousness
    - iii. Psychosis
    - iv. Suicidal behavior

E&I Review Services
IRB Study #20070
05/12/2021

l. Respiratory
i. Bronchospasm
o Risks associated with azithromycin
m. Dermatologic
i. Generalized rash
ii. Pruritis
iii. Photosensitivity reaction
iv. Stevens-Johnson syndrome
v. Urticaria
vi. Dermatitis
vii. Dry Skin
viii. Hyperhidrosis
ix. Eczema
x. DRESS
xi. Toxic epidermal necrolysis
xii. Erythema multiforme
xiii. Fungal dermatitis
xiv. Sweating
xv. Vesiculobullous rash
xvi. Maculopapular rash
n. Gastrointestinal
i. Diarrhea
ii. Nausea
iii. Vomiting
iv. Abdominal pain
v. Loose stools
vi. Flatulence
vii. Dyspepsia
viii. Stomatitis
ix. Gastroenteritis
x. Oral candidiasis
xi. Constipation
xii. Dysphagia/oral dysphagia
xiii. Abdominal distention
xiv. Dry mouth
xv. Eructation
xvi. Mouth ulceration
xvii. Salivary hypersecretion
xviii. Pseudomembranous colitis
xix. Pancreatitis
xx. Tongue discoloration
xxi. Melena
xxii. Enteritis
xxiii. Abnormal stools
xxiv. Gastrointestinal disorders
xxv. Pyloric stenosis
o. Genitourinary
i. Vaginitis
ii. Vaginal infection
iii. Dysuria
iv. Intermenstrual bleeding
v. Testicular disorders
p. Hematologic
i. Lymphopenia
ii. Decreased hematocrit
iii. Decreased hemoglobin
iv. Neutropenia
v. Eosinophilia
vi. Increased platelet count
vii. Increased hematocrit
viii. Increased lymphocytes
ix. Increased basophils
x. Increased monocytes
xi. Increased neutrophils
xii. Thrombocytopenia
xiii. Anemia/Hemolytic anemia
xiv. Decreased platelet count
q. Hepatic
i. Hepatitis
ii. Increased AST, ALT, GGT, or blood bilirubin
iii. Hepatic failure
iv. Fulminant hepatitis
v. Hepatic necrosis
r. Hypersensitivity
i. Allergic reaction
ii. Angioedema
iii. Hypersensitivity
iv. Anaphylactic reaction
s. Immunologic
i. Moniliasis
ii. Flu syndrome
t. Metabolic
i. Decreased bicarbonate
ii. Anorexia
iii. Hypernatremia
iv. Elevated alkaline phosphatase
v. Elevated bicarbonate
vi. Hypochloridemia
vii. Elevated lactate dehydrogenase
viii. Hyponatremia
ix. Hypokalemia
x. Dehydration
u. Musculoskeletal
i. Arthralgia
ii. Osteoarthritis
iii. Myalgia
iv. Back pain

E&I Review Services
IRB Study #20070
05/12/2021

v. Neck pain
vi. Elevated creatinine kinase
v. Nervous system
i. Headache
ii. Dizziness
iii. Paresthesia
iv. Dysgeusia
v. Somnolence
vi. Hypesthesia
vii. Syncope
viii. Convulsion
ix. Anosmia
x. Ageusia
xi. Parosmia
xii. Vertigo
xiii. Myasthenia gravis
xiv. Taste perversion
xv. Hyperkinesia
xvi. Hyperactivity
w. Optical
i. Visual impairment
ii. Conjunctivitis
x. Other
i. Deafness
ii. Fatigue
iii. Candidiasis
iv. Otic disorders
v. Asthenia
vi. Malaise
vii. Facial edema
viii. Pyrexia
ix. Pain
x. Post-procedural complications
xi. Fungal or bacterial infection
xii. Mucositis
xiii. Fever
xiv. Chills
y. Psychiatric
i. Nervousness
ii. Insomnia
iii. Agitation
iv. Aggression
v. Anxiety
vi. Delirium
vii. Hallucination
viii. Emotional lability
ix. Irritability
x. Hostility
z. Renal
i. Nephralgia
ii. Elevated BUN and creatinine
iii. Acute renal failure
iv. Interstitial nephritis
aa. Respiratory
i. Dyspnea
ii. Pneumonia
iii. Pharyngitis
iv. Rhinitis
v. Epistaxis
vi. Bronchospasm
vii. Cough
viii. Pleural effusion
ix. Asthma
x. Bronchitis
xi. Reactive airway

- Risks associated with Vitamin C

a. Common side effects
i. Diarrhea
ii. Nausea
iii. Vomiting
iv. Abdominal cramps/pain
v. Heartburn
b. Serious side effects
i. Painful urination
ii. Pink or bloody urine
iii. Allergic reaction: including rash, itching, swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing

- Risks associated with Vitamin D

a. Common side effects
i. None
b. Serious side effects
i. Vomiting
ii. Nausea
iii. Constipation
iv. Altered blood calcium levels
v. Increased thirst
vi. Increased urination
vii. Mental/mood changes
viii. Unusual tiredness
ix. Allergic reaction: including rash, itching, swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing

- Risks associated with zinc
    i. Nausea
    ii. Vomiting
    iii. Constipation
    iv. Changes in blood calcium levels
    v. Increased thirst
    vi. Increased urination
    vii. Mental status/mood changes
    viii. Fatigue
    ix. Kidney damage
    x. Stomach damage
    xi. Allergic reaction: rash, pruritis, edema (especially of the face/tongue/throat), severe dizziness, dyspnea

The medications may not be effective in preventing symptoms of COVID-19. You must continue to take all CDC recommended precautions.

- Risks Associated with Confidentiality

In the event of a security or data breach or a failure to follow protocol, your data, survey responses, or other personally identifying information could be compromised. This could be a physical breach of lab and storage facilities, compromising of data storage, or a failure to follow protocol. If a physical sample is stolen or mishandled by an employee or contractor, they may be able to obtain additional information from the sample such as sequencing your DNA. If data are compromised, it could be possible to connect your data with your identity.

If you choose to share information from this Research Study with your health care providers, that information could become part of your medical record. Information contained in the medical record may become available to other medical professionals or insurance companies.

- Conflict of Interest

The Chief Scientific Officer of ProgenaBiome, LLC, a private company, is also the head of research, or Primary Investigator. While there could arise a conflict of interest for this person, the duties of the Primary Investigator come first, and the interests of the research are held above those of the company for the purposes of the Research Study.

- Risks Associated with Blood Draw

If you have a blood test for blood G6PD deficiency, the risks of blood draw include but are not limited to, momentary discomfort at the site of the blood draw, possible bruising, redness, and swelling around the site, bleeding at the site, feeling of lightheadedness when the blood is drawn, fainting, and rarely, an infection at the site of the blood draw.

- Risks Associated with Pregnancy

If you are a woman of childbearing potential, you must use 2 forms of birth control. Acceptable forms include: condoms with spermicide, oral birth control pills, contraceptive implants, intra-uterine devices, or diaphragms. At least one of these must be a barrier method. There may be risks to the fetus or nursing infants while taking the study medication. If you become pregnant stop the study medication and contact the Principal Investigator listed on Page 2 and your medical provider.

- There may be other risks that are not currently foreseeable.

E&I Review Services
IRB Study #20070
05/12/2021

Prohibited Medications

abarelix
abiraterone
acetohexamide
adalimumab
adenosine
ado-trastuzumab emtansine
albuterol
alfuzosin
aluminum carbonate
aluminum hydroxide
amifampridine
amiodarone
amisulpride
amitriptyline
amoxapine
anagrelide
apalutamide
apomorphine
arformoterol
aripiprazole
arsenic trioxide
asenapine
astemizole
atomoxetine
atorvastatin
attapulgite
auranofin
aurothioglucose
bedaquiline
benznidazole
bepridil
bicalutamide
bisacodyl
bitolterol
bortezomib
bosutinib
brentuximab
buprenorphine
cabazitaxel
cabozantinib
calcium carbonate
carboplatin
carfilzomib
casanthranol
cascara sagrada
castor oil
ceritinib
cerivastatin
certolizumab
cevimeline
chloramphenicol
chloroquine
chlorpromazine
chlorpropamide
cimetidine
ciprofloxacin
cisapride
cisplatin
citalopram
clarithromycin
clofazimine
clomipramine
clozapine
codeine
colchicine
crizotinib
dapsone
darifenacin
dasatinib
daunorubicin
daunorubicin liposomal
deferiprone
degarelix
desipramine
deutetrabenazine
didanosine
digoxin
dihydroxyaluminum sodium carbonate
dinutuximab
disopyramide
disulfiram
docetaxel
dofetilide
dolasetron
donepezil
doxepin
doxepin topical
doxorubicin
doxorubicin liposomal
dronedarone
droperidol
duloxetine efavirenz
elotuzumab
encorafenib
enfortumab vedotin
entrectinib
enzalutamide
epirubicin
eribulin
erythromycin
escitalopram
etanercept
ethambutol
ethionamide
etoposide
etravirine
ezogabine
famotidine
fesoterodine
fingolimod
flecainide
fluconazole
fludarabine
fluoxetine
fluphenazine
flutamide
fluvastatin
formoterol
foscarnet
galantamine
gatifloxacin
gemifloxacin
gilteritinib
glasdegib
glimepiride
glipizide
glyburide
glycerin
gold sodium thiomalate
golimumab
goserelin
granisetron
grepafloxacin
ibutilide
idarubicin
iloperidone
imipramine
indacaterol
infliximab
inotuzumab ozogamicin
interferon alfa-2a
interferon alfa-2b
interferon alfa-n1
interferon alfacon-1
iodoquinol
ipilimumab
isoetharine
isoniazid
isoproterenol
ivabradine
ivosidenib
ixabepilone
ixazomib
kaolin
ketoconazole
lactitol
lactulose
lanthanum carbonate
lapatinib
lefamulin
leflunomide
lenvatinib
leuprolide
levalbuterol
levodopa
levofloxacin
levomethadyl acetate
linezolid
lithium
lofexidine
lomefloxacin
loperamide
lovastatin
macimorelin
magaldrate
magnesium carbonate
magnesium citrate
magnesium hydroxide
magnesium oxide
maprotiline
mefloquine
mesoridazine
metaproterenol



methadone
methotrexate
methotrimeprazine
metoprolol
metronidazole
midostaurin
mifepristone
mineral oil
mirtazapine
moxifloxacin
nateglinide
nelarabine
nilotinib
nilutamide
nitrofurantoin
norfloxacin
nortriptyline
ofloxacin
olanzapine
olodaterol
ondansetron
osilodrostat
osimertinib
oxaliplatin
paclitaxel
paclitaxel protein-bound
paliperidone
palonosetron
panobinostat
papaverine
pasireotide
pazopanib
peginterferon alfa-2a
peginterferon alfa-2b
penicillamine
pentamidine
perflutren
perphenazine
phenolphthalein
pimavanserin
pimozide
pirbuterol
pitavastatin
pitolisant
polatuzumab vedotin
polyethylene glycol 3350
polyethylene glycol 3350 with electrolytes
pomalidomide
ponatinib
posaconazole
pravastatin
primaquine
probucol
procainamide
prochlorperazine
promazine
promethazine
propafenone
propofol
propoxyphene
protriptyline
quetiapine
quinapril
quinidine
quinine
rabies vaccine, human diploid cell
rabies vaccine, purified chick embryo cell
ranolazine
red yeast rice
repaglinide
ribociclib
rilpivirine
risperidone
ritodrine
rivastigmine
romidepsin
rosuvastatin
salmeterol
saquinavir
secnidazole
senna
sertraline
sevoflurane
simvastatin
siponimod
sodium iodide i-123
sodium iodide-i-131
solifenacin
sorafenib
sotalol
sparfloxacin
stavudine
sulfamethoxazole
sunitinib
tacrine
tacrolimus
tamoxifen
telavancin
telbivudine
telithromycin
teniposide
terbutaline
terfenadine
teriflunomide
tetrabenazine
thalidomide
thioridazine
timolol ophthalmic
tinidazole
tizanidine
tocilizumab
tolazamide
tolbutamide
tolterodine
toremifene
trabectedin
tramadol
trazodone
triclabendazole
trifluoperazine
triflupromazine
trimeprazine
trimipramine
triptorelin
typhoid vaccine, live
valbenazine
vandetanib
vardenafil
vasopressin
vemurafenib
venlafaxine
vigabatrin
vinblastine
vincristine
vincristine liposome
vinorelbine
voriconazole
zafirlukast
zalcitabine
zidovudine
ziprasidone

Compensation

You will not be compensated for participation. You will not be compensated for any products, services, or intellectual property developed as a result of this Research Study.

Alternatives

There are no FDA-approved therapies to prevent symptoms of COVID-19 infection. However, the FDA has granted Emergency Use Authorization for vaccines, which have been shown to be effective against COVID-19 infection. Vaccination will protect most people from getting infected.

Your alternative is not to participate in this study.

Voluntary Participation and Withdrawal
Your participation in this Research Study is completely voluntary, and you may stop participating at any time. If you decide not to participate or decide to withdraw from the study, there will be no penalty or loss of benefits to which you are otherwise entitled. The Research Study doctor or sponsor may remove you from the Research Study at any time without your consent. The Research Study may also be terminated without your consent. If this happens your samples and information will be stored according to the terms of this document

If you decide to stop participating with this Research Study, please contact the Principal Investigator listed on Page 2. Any data collected up to the point of withdraw will be kept as part of the study database. No new information will be collected.

Research already completed or published will not be undone, withdrawn, or revised.

Who can answer questions about this research?
If you have questions, concerns, or complaints, to offer input or think this research has hurt you or made you sick, talk to the research team at 805-339-0549 or 24-hour number 800-920-0016.

This research is being overseen by an Institutional Review Board ("IRB"). An IRB is a group of people who performs independent review of research studies. You may contact Ethical and Independent Review Services (E&I) IRB that reviewed this study (reference E&I study 20070) at (800) 472-3241 or subject@eandireview.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

What if I am injured because of taking part in this research?
If you are injured or get sick because of being in this research, call Dr. Sabine Hazan immediately at 805-339-0549 or 24-hour number 800-920-0016. The study doctor will provide emergency medical treatment. Your insurance may be billed for this treatment. If you do not have insurance or your insurance will not pay for the cost of the treatment, ProgenaBiome will cover the cost of treatment.

What your Agreement Means:

1. You are consenting to take part in this Research Study
2. The Research Study was explained to you
3. You have been provided a copy of your rights as a research participant
4. You have fully read this consent
5. You do not give up your legal rights by agreeing to take part, and the researcher(s) or sponsor(s) are not relieved of any liability
6. If any new information arises which may affect your health or willingness to stay in the Research Study, ProgenaBiome, LLC will inform you

Please select from the following choices:

☐ **I agree to participate**
☐ **ProgenaBiome, LLC, or its affiliates, may contact me in for the future to ask if I would like to participate in additional research**
☐ **I give permission for my samples and data to be used for future research and shared with other researchers**
☐ **I do not give permission for my samples and data to be used for future research**

_____ _____
Participant's Name **Today's Date**

_____
Participant's Signature

I have discussed this consent form and study-related activities with this participant. Any questions raised by the participant have been answered. In my judgment, the participant is giving both voluntary and informed consent.

_____ _____
Name of Person Conducting Consent **Signature of Person Conducting Consent**

_____
Today's Date

*You will receive a copy of this signed consent document



E&I Review Services
IRB Study #20070
05/12/2021

Health Insurance Portability and Accountability Act (HIPAA) Authorization

Title of Research Study: A Randomized, Double-Blind, Placebo-Controlled Phase IIa Study of Hydroxychloroquine, Vitamin C, Vitamin D, and Zinc for the Prevention of COVID-19 Infection

Brief Title: HELP COVID-19

Protocol #: ProgenaBiome-042
Sponsor: ProgenaBiome, LLC

Introduction

The purpose of this document is to inform you regarding how your protected health information (PHI) and medical records will be used for the Research Study, and how they may be shared. Please ask ProgenaBiome, LLC to explain any words or information that is unclear to you. You do not need to make a decision right away and may consult with others before making your decision. You may choose not to sign this form. If you choose not to sign this form, you cannot participate in the Research Study. If you do choose to participate, you will receive a copy of this signed and dated form for your records.

This form allows your health care provider to share your information as described previously in the Research Study consent form. You have rights regarding your protected health information and medical records. You have a right to view your medical records and know who else is viewing them and why. If you choose to participate in this Research Study and sign this form, it will give your health care provider permission to share your protected health information with ProgenaBiome, LLC.

ProgenaBiome, LLC may then share that information with its researchers and regulatory agencies. This document will describe this in detail so that you can make an informed decision whether you would like to participate in the research.

E&I Review Services
IRB Study #20070
05/12/2021

Your Rights as A Research Study Participant

1. You have the right to be informed of the purpose of the experiment
2. You have the right to be informed of the nature of the experiment
3. You have the right to ask questions about the experiment and its procedures
4. You have the right to be informed of any possible benefits to you from the experiment
5. You have the right to be informed of any treatments available to you, should any complications arise after the experiment is over
6. You have the right to withdraw permission at any time
7. You have the right to receive a copy of your signed and dated consent form
8. You have the right to decide whether to participate in this Research Study without any undue influence, including force, deceit, or coercion.

What Information We Are Referring To

For the purposes of this Research Study, the following information may be reviewed and collected. This may include the following:

1. Your COVID-19 testing status
2. Information requested by ProgenaBiome, LLC from your medical records

You Have a Right to Your Own Medical Record

This includes viewing and making a copy of your records.

Who Will Receive This Information and Why?

By signing this form, you agree to let your health care provider share your medical records with the sponsor of the Research Study, and the sponsor's representatives. These are the people who will collect data from your records and then the sponsor will analyze these data. Your name, address, and social security number are NOT included with this information.

Regulatory agencies may review the data from this Research Study to make sure your privacy is being protected. The Institutional Review Board (IRB) may review the data from this Research Study to make sure your rights are being protected.

If the results of this Research Study are published in scientific journals, your name and other identifying information will not be included.

How Do We Protect Your Privacy Rights?

We will only use the information you give us for the purposes described here and in the Research Study consent form. We will only share that information as described above, and each of those groups has an obligation to protect your information.

Could You Be Identified from the Information We Use?

It is possible, although highly unlikely, that technology in the future could allow a person to compare information about you or a close relative to our databases and find your information. It is also possible, although unlikely, that the security of the databases could be compromised, allowing those without access to see the codes which link your personal information to your test results.

Will my authorization expire?

If you do not withdraw this Authorization, it will remain in effect until 31 December, 2025.

You May Withdraw Permission at Any Time

This can be done by writing to ProgenaBiome, LLC at support@progenabiome.com. You will no longer be able to participate in the Research Study if you do this. Once ProgenaBiome, LLC has received your request to stop participating (withdraw consent), we will process that request and cease use of your data and samples for new research within 30 days from your request. Any information sent to the sponsor prior to this date may still be used, but without any identifying information.

What I Am Authorizing

By signing this Authorization form, I am not giving up any of my legal rights.
I am authorizing the disclosure and use of my Protected Health Information as described above.

_____

Participant's Name (please print)

_____ _____

Signature of Participant Date



E&I Review Services
IRB Study #20070
05/12/2021