Camostat and Artemisia Annua vs Placebo in COVID-19 Outpatients

ClinicalTrials.gov Identifier: NCT04530617

Recruitment Status : Recruiting
First Posted : August 28, 2020
Last Update Posted : October 22, 2020

See **Contacts and Locations**

Sponsor:
Instituto Nacional de Ciencias Medicas y Nutricion Salvador Zubiran

Collaborators:

Instituto Nacional de Cardiologia Ignacio Chavez

Hospital General de Mexico

Hospital General Dr. Manuel Gea González

Information provided by (Responsible Party):

Instituto Nacional de Ciencias Medicas y Nutricion Salvador Zubiran

Study Description

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Brief Summary:

This is a randomized, double-blind, placebo-controlled, multi-arm, multicenter, phase II trial design to allow a rapid efficacy and toxicity assessment of potential therapies (camostat mesilate and artemisia annua) immediately after COVID-19 positive testing in mild to moderate disease and high-risk factors such as diabetes, hypertension, and obesity among others.

Condition or disease	Intervention/treatment	Phase
Covid19 Diabetes Hypertension Obesity	Drug: Camostat Mesilate Drug: Artemisia Annua Leaf	Phase 2

Detailed Description:

Coronavirus Disease 2019 (COVID-19) is a highly contagious disease, caused by a novel enveloped RNA beta-coronavirus, also known as severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2). This disease has caused a global health crisis.

While the majority of patients with COVID-19 develop a mild or uncomplicated illness, approximately 20-30% of hospitalized patients have required intensive care support and 5% of those have multi-organ failure or shock. The case fatality rate ranges from 1 to 4% and it is higher

among those with pre-existing comorbid conditions (high-risk) such as cardiovascular disease, diabetes mellitus, obesity, chronic respiratory disease, hypertension, and cancer.

To date, treatments for COVID-19 in high-risk individuals remain experimental and therapeutic strategies to deal with the infection are at best supportive, with prevention aimed at reducing transmission in the community as the best weapon. No proven therapies have been demonstrated to prevent progression of COVID-19 to severe illness in confirmed outpatients with COVID-19 and this is a critical unmet need for high-risk individuals and warrants study. Furthermore, there are no effective medications for the use in outpatients with confirmed mild to moderate COVID-19 disease.

This is a randomized, double-blind, placebo-controlled, multi-arm, multicenter, phase II trial design to allow a rapid efficacy and toxicity assessment of potential therapies, camostat mesilate (serine protease inhibitor) and Artemisia annua (unknown mechanism) immediately after COVID-19 positive testing in mild to moderate disease and high-risk factors such as diabetes, hypertension, and obesity among others. The hypothesis of this study is that the addition of agents that inhibit viral entry or replication of SARS-CoV-2 virus, such as Artemisia annua and camostat, will reduce the rate of a composite outcome of hospitalization due to COVID-19 pneumonia or the use of oxygen therapy; will be devoid of additional moderate to severe toxicities; and will improve viral clearance at Day 14 in high-risk individuals. The main hypothesis is that the clinical outcomes in COVID-19 infected patients at higher risk of poor outcomes following infection will be improved compared to the standard of care when introduced as an early intervention after diagnosis.

Study Design

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Study Type :	Interventional (Clinical Trial)
Estimated Enrollment :	360 participants
Allocation:	Randomized
Intervention Model:	Parallel Assignment
Intervention Model Description:	A randomized, placebo-controlled, parallel, multicenter, multi-arm, phase II trial of novel agents for treatment of high-risk COVID-19 positive outpatients. Subjects who meet the inclusion/exclusion criteria and have properly signed the informed consent will be randomized to the test group or placebo group in the ratio of 1:1:1:1.
Masking:	Triple (Participant, Care Provider, Investigator)

Masking Description:	The masking of the protocol will be maintained throughout the duration of the study. This will be done with the use of a matched placebo and a non-continuous coding (tablets in the case of camostat and tea bags/coffer for Artemisia) that has the same description and dose as the interventions so that both, the investigators and the patient does not know the treatment assignment.
Primary Purpose:	Treatment
Official Title:	Randomized, Double-blind, Placebo-controlled, Multicenter, Multi-arm, Phase II Trial of Novel Agents for the Treatment of Mild to Moderate COVID-19 Positive Outpatients
Actual Study Start Date :	October 5, 2020
Estimated Primary Completion Date :	January 2021
Estimated Study Completion Date :	February 2021

Resource links provided by the National Library of Medicine

MedlinePlus Genetics related topics: Hypertension

U.S. FDA Resources

Arms and Interventions

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Arm	Intervention/treatment
Active Comparator: Camostat mesilate 100 mg tablet, 600 mg/day. Oral, 2 tablets three times a day, after a meal (600 mg total daily dose) Days 1-14.	Drug: Camostat Mesilate Tablets Other Name: Camostat
Placebo Comparator: Camostat Placebo Matched placebo	Drug: Camostat Mesilate Tablets Other Name: Camostat

Arm	Intervention/treatment
Active Comparator: Artemisia annua Tea 225mg per bag,1350 mg/day. Oral, one 8 oz brewed tea (two bags) three times a day, Days 1-14.	Drug: Artemisia Annua Leaf Tea bags Other Names: • Artemisia annua • Artemisia
Placebo Comparator: Artemisia annua Placebo Matched placebo	Drug: Artemisia Annua Leaf Tea bags Other Names: • Artemisia annua • Artemisia

Outcome Measures

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Primary Outcome Measures :

1. Rate of hospitalizations and oxygen use [Time Frame: 14 days]

   Decrease in a composite outcome of hospitalization and supplemental oxygen use at day 14 between treatment pairs.

Eligibility Criteria

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Information from the National Library of Medicine

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, Learn About Clinical Studies.

Ages Eligible for Study:	18 Years and older (Adult, Older Adult)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Age ≥18 years
- Laboratory-confirmed SARS-CoV-2 infection within 3 days (of proposed consent) or the presence of symptoms or signs providing a high probability of COVID-19 disease who have symptoms within 7 days prior to diagnosis as determined by Infectious Disease specialist or treating physicians.
- Outpatients. No previous hospitalization within the past 3 months.
- Subjects must have at least one of the following high-risk features for clinical deterioration:
  - Hypertension
  - Diabetes mellitus
  - Moderate to severe Chronic Obstructive Pulmonary Disease or asthma
  - Cancer patients who have received any immunosuppressive drugs within a year from enrollment.
  - Obesity as defined by a body mass index > 30 kg/m2.
  - Living in a nursing home or long-term facility
  - Underlying serious heart condition as determined by the treating physician
  - Immunocompromised subject as defined by the treating physician or by the Infectious Disease specialist

- Ability to provide informed consent by the patient or healthcare proxy.
- Ability to return for repeated testing and observation to the hospital.
- Patients must have adequate organ and marrow function measured within the last 30 days as defined below:

- platelets ≥100,000
- aspartate transaminase or alanine transaminase ≤3 times institutional upper limit of normal
- creatinine ≤ 1.5 times institutional upper limit of normal OR
- glomerular filtration rate ≥45 mL/min/1.73 m2 unless data exists supporting safe use at lower kidney function values, no lower than 30 mL/min/1.73 m2

Exclusion Criteria:

- Severe COVID-19 is defined by one or more of the following:
  - blood oxygen saturation ≤ 90%
  - partial pressure of arterial oxygen to fraction of inspired oxygen ratio < 300
  - lung infiltrates ≥ 50% within 24 to 48 hours
- Life-threatening COVID-19 is defined as one or more of the following:
  - respiratory failure
  - septic shock
  - multiple organ dysfunction or failure
- Weight less than 45 kg.
- Pregnant or breast-feeding females
- Subjects on dialysis or with creatinine clearance < 45 ml/min
- Subjects who need antiviral administration due to severe viral diseases other than COVID-19, such as HIV, hepatitis B, and hepatitis C
- Existing Division of Microbiology and Infectious Disease Toxicity Scale for determining the severity of adverse events grade 3 or greater.
- Uncontrolled seizure disorder
- Subjects with reflux esophagitis after chronic pancreatitis and gastrectomy surgery.

- Patients with reflux esophagitis after surgery.
- Known allergy to Artemisia annua or camostat mesilate.
- Currently receiving any study medications for other indications.
- Concurrent use of medication that would cause moderate or severe due to drug-drug interactions with study medication.

Specifically:

- Patients receiving Artemisia annua tea may not be currently taking strong inducers of CYP2A6, including phenobarbital and rifampin.
- Receipt in the 12 hours prior to enrollment, or planned administration during the 14-day study period that treating clinicians feel cannot be substituted for another medication, of any of the following: amiodarone; cimetidine; dofetilide; phenobarbital; phenytoin; or sotalol.
- Cancer patients receiving active immunosuppressive treatment cannot be enrolled unless they are on a treatment holiday with no antineoplastic treatment with 3 weeks of enrollment.
- Patients with genetic problems such as galactose intolerance, Lapp lactase deficiency, or glucose-galactose malabsorption
- Subjects who have a history of drug and/or alcohol abuse within 52 weeks before screening
- Enrollment on other experimental therapies for COVID-19.
- Inability to receive enteral medications
- Patients with psychiatric illness/social situations that would limit compliance with study requirements.
- Subjects who have a history of drug and/or alcohol abuse within 52 weeks before screening
- Any other condition that in the opinion of the treating physician justifies exclusion from the study.

Contacts and Locations

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Information from the National Library of Medicine

To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT04530617***

Contacts

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Locations

Mexico

Instituto Nacional de Ciencias Médicas y Nutrición Salvador Zubirán **Recruiting**

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Investigators

Principal Investigator: Jose G Gotes Palazuelos, MD Instituto Nacional de Ciencias Medicas y Nutricion Salvador Zubiran

More Information

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Additional Information:

ohns Hopkins University of Medicine Coronavirus Resource Center Map EXIT

14. COVID-19 Treatment Guidelines Panel. Coronavirus Disease 2019 (COVID-19) Treatment Guidelines. National Institutes of Health.

WHO supports scientifically-proven traditional medicine.

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Responsible Party: Instituto Nacional de Ciencias Medicas y Nutricion Salvador Zubiran

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Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD:	No
Plan Description:	All IPD results in the publication

Studies a U.S. FDA-regulated Drug Product:	No
Studies a U.S. FDA-regulated Device Product:	No

Keywords provided by Instituto Nacional de Ciencias Medicas y Nutricion Salvador Zubiran:

Covid19
Outpatients
High-risk

Additional relevant MeSH terms:

Hypertension
Vascular Diseases
Cardiovascular Diseases
Camostat
Protease Inhibitors
Enzyme Inhibitors
Molecular Mechanisms of Pharmacological Action
Trypsin Inhibitors
Serine Proteinase Inhibitors