Fluvoxamine for Early Treatment of Covid-19 (Stop Covid 2)

CLINICAL TRIALS

Washington University School of Medicine

Abstract

The purpose of this research study is to determine if a drug called fluvoxamine can be used early in the course of the COVID-19 infection to prevent more serious complications like shortness of breath. Fluvoxamine is an anti-depressant drug approved by the FDA for the treatment of obsessive-compulsive disorder. The use of fluvoxamine for the treatment of COVID-19 is considered investigational, which means the US Food and Drug Administration has not approved it for this use. This study is fully-remote, which means that there is no face-to-face contact; study materials including study drug will be shipped to participants' houses. People around the United States and Canada can participate.

Description

The investigators will randomize approximately 880 participants, age 30 and older, who have tested tested positive for COVID-19 and are currently experiencing mild symptoms. People around the United States and Canada can participate. All interactions for this study will be conducted remotely by videoconferencing, email, or phone. Screening: All participants will first complete a pre-screen to see if they may be eligible for the study. Once a participant is confirmed eligible and consented, the study team will send the study materials. These materials will consist of study medication and self-monitoring equipment, including an oxygen saturation monitor, blood pressure monitor, and thermometer. RCT: Participants will be randomly assigned (1:1) to take either fluvoxamine or a placebo. This phase of the study will last approximately 15 days and is double-blinded. Participants will take up to 100mg of fluvoxamine or placebo by mouth twice a day for a daily total of 200mg. Participants will continue this dose for approximately 15 days. Depending on tolerability, the dose may be adjusted. Participants will also complete short 5 minute assessments daily to report the results of self-monitoring (including oxygen level, blood pressure, and temperature), a shortness of breath rating and any adverse events. Follow-up Phase: The study team will follow participants for approximately 90 days after the end of the randomized phase. If needed, the study team will review medical records to determine the clinical course of participants.

Eligibility

Eligibility Criteria

All

HIGHLIGHTS

Tags

- Fluvoxamine
- Obsessive–compulsive disorder
- Videoconferencing
- Oxygen saturation
- Sphygmomanometer
- Thermometer

Eligibility Tags

- Severe acute respiratory syndrome
- Fever
- Myalgia
- Dyspnea
- Chest pain
- Diarrhea
- Nausea
- Anosmia
- Ageusia
- Pharyngitis
- Nasal congestion
- Obesity
- Hypertension
- Diabetes mellitus
- Cardiovascular disease
- Infarction
- Heart failure
- Asthma
- Chronic obstructive pulmonary disease

Eligible Gender

30

Minimum Age

Not Accepted

Healthy Volunteers

Conditions

Covid19

Conditions

Coronavirus

Conditions

Interventions

Fluvoxamine

Intervention Name

Up to 200mg per day (2 capsules per day) as tolerated, for approximately 15 days

Intervention Description

Drug

Type

Placebo

Intervention Name

Will take 2 capsules per day as tolerated for approximately 15 days

Intervention Description

Drug

Type

Outcomes

Primary Outcome

Outcome Type

Defined as both of the following: 1)Presence of dyspnea and/or hospitalization for shortness of breath or pneumonia, 2)) decrease in O2 saturation (<92% on room air) and/or supplemental oxygen requirement to keep O2 saturation ≥92%).

Outcome Description

Immunodeficiency

Sponsors

Washington University School of Medicine

Status

Recruiting

Phase

Phase 3

Last Updated

2021-03-01

External Resources

ClinicalTrials.gov

Clinical deterioration

Outcome Measure

RCT-approximately 15 days

Outcome Time Frame

Secondary Outcome

Outcome Type

Self report post Covid Functioning using the PROMIS Global Health Scale. It is a 10-item patient-reported questionnaire in which the response options are presented as 5-point, and one 11-point, rating scales. Higher scores indicate better health.

Outcome Description

Post Covid Functioning

Outcome Measure

Day 15 and Day 90

Outcome Time Frame

Sponsors

Washington University School of Medicine

Sponsor Name

Primary Sponsor

Type

University

Organization Type

Study Details

Interventional

Study Type

Parallel Assignment

Intervention Model

Treatment

Primary Purpose

Contacts

Contacts not available.

Citations

Citations not available.

Eligibility Tags

- Severe acute respiratory syndrome
  Eligibility Tags
- Fever
  Eligibility Tags
- Myalgia
  Eligibility Tags
- Dyspnea
  Eligibility Tags
- Chest pain
  Eligibility Tags
- Diarrhea
  Eligibility Tags
- Nausea
  Eligibility Tags
- Anosmia
  Eligibility Tags
- Ageusia
  Eligibility Tags
- Pharyngitis
  Eligibility Tags
- Nasal congestion
  Eligibility Tags
- Obesity
  Eligibility Tags
- Hypertension
  Eligibility Tags
- Diabetes mellitus
  Eligibility Tags

- Cardiovascular disease
  Eligibility Tags
- Infarction
  Eligibility Tags
- Heart failure
  Eligibility Tags
- Asthma
  Eligibility Tags
- Chronic obstructive pulmonary disease
  Eligibility Tags
- Immunodeficiency
  Eligibility Tags
- Rheumatoid arthritis
  Eligibility Tags
- Systemic lupus erythematosus
  Eligibility Tags
- Oxygen
  Eligibility Tags
- Oxygen therapy
  Eligibility Tags
- Comorbidity
  Eligibility Tags
- Cirrhosis
  Eligibility Tags
- Organ transplantation
  Eligibility Tags
- Hematopoietic stem cell transplantation
  Eligibility Tags
- HIV
  Eligibility Tags
- Biologic medical product
  Eligibility Tags

- Corticosteroid
  Eligibility Tags
- Prednisone
  Eligibility Tags
- Preventive medicine
  Eligibility Tags
- Donepezil
  Eligibility Tags
- Agonist
  Eligibility Tags
- Sertraline
  Eligibility Tags
- Sigma-1 receptor
  Eligibility Tags
- Receptor antagonist
  Eligibility Tags
- Warfarin
  Eligibility Tags
- Phenytoin
  Eligibility Tags
- Fluvoxamine
  Eligibility Tags
- Liver
  Eligibility Tags
- Clopidogrel
  Eligibility Tags
- Prodrug
  Eligibility Tags
- Wort
  Eligibility Tags
- Serotonin syndrome
  Eligibility Tags

- Selective serotonin reuptake inhibitor
  Eligibility Tags
- Serotonin–norepinephrine reuptake inhibitor
  Eligibility Tags
- Tricyclic antidepressant
  Eligibility Tags
- Escitalopram
  Eligibility Tags
- Amitriptyline
  Eligibility Tags
- QT interval
  Eligibility Tags
- Bipolar disorder
  Eligibility Tags
- Lithium (medication)
  Eligibility Tags
- Antipsychotic
  Eligibility Tags
- Mania
  Eligibility Tags
- Alprazolam
  Eligibility Tags
- Diazepam
  Eligibility Tags
- Theophylline
  Eligibility Tags
- Tizanidine
  Eligibility Tags
- Clozapine
  Eligibility Tags
- Olanzapine
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CYP1A2

Eligibility Tags

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