

A Study to Learn About the Study Medicine Ibutatrelvir in Adults With COVID-19 Who Are Severely Immunocompromised

NCT07013474

Status	RECRUITING
Phase	Phase 3
Sponsor	Pfizer
Enrollment	300 participants

Key Eligibility Criteria

Inclusion (7)

- years of age or older at screening who are non-hospitalized or hospitalized for observation or with the intent of administering the study intervention.
- Confirmed SARS-CoV-2 infection as determined by RAT (or other locally approved test) collected within 2 days prior to randomization. Initial onset of symptoms attributable to COVID-19 within 5 days prior to the day of randomization and at least 1 of the specified symptoms attributable to COVID-19 present on the day of randomization.
- Severely immunocompromised due to:
- Solid organ or islet cell transplant recipient who is receiving immunosuppressive therapy;
- Active hematologic malignancy (eg, chronic lymphocytic leukemia, non-Hodgkin lymphoma, multiple myeloma, acute leukemia);
... and 2 more (see full listing online)

Exclusion (13)

- Severe COVID-19, or current need for supplemental oxygen for treatment of COVID-19.
- Receiving dialysis or have current kidney failure (ie, eGFR consistently <15 mL/min/1.73 m²)
- Active liver disease
- History of hypersensitivity or other contraindication to any of the components of the study interventions, as determined by the investigator
- Suspected or confirmed concurrent active systemic infection other than COVID-19 that may interfere with the evaluation of response to the study intervention.
... and 8 more (see full listing online)

Locations (117 total)

Hope Clinical Research, Inc., Canoga Park, California, United States
Amicis Research Center - Granada Hills, Granada Hills, California, United States
UC Davis CTSC Clinical Research Center, Sacramento, California, United States
... and 114 more locations