

A Clinical Study of Molnupiravir to Prevent Severe Illness From Coronavirus Disease 2019 (COVID-19) in People Who Are High Risk (MK-4482-023)

NCT06667700

Status	RECRUITING
Phase	Phase 3
Sponsor	Merck Sharp & Dohme LLC
Enrollment	3,082 participants

Key Eligibility Criteria

Inclusion (18)

- Is an individual of any sex/gender, e18 years of age
- Has documentation of SARS-CoV-2 infection with sample collection d4 days prior to randomization
- Has initial onset of signs/symptoms attributable to COVID-19 for d4 days prior to the day of randomization and e2 of the following signs/symptoms attributable to COVID-19 on the day of randomization: cough, sore throat, nasal congestion, shortness of breath or difficulty breathing with exertion, muscle or body aches, fatigue, fever $\geq 38.0^{\circ}\text{C}$ or chills, nausea or vomiting or diarrhea, change in sense of smell or change in sense of taste, or headache
- Has e1 of the following characteristics or medical conditions associated with the highest risk of severe illness from COVID-19:
- Advanced age of e75 years of age
- ... and 13 more (see full listing online)

Exclusion (11)

- Is currently hospitalized or is expected to need hospitalization for COVID-19 imminently
- Has received or plans to receive SARS-CoV-2 directed oral antivirals or monoclonal antibodies for current episode of COVID-19 (other than study intervention and, if applicable, remdesivir as standard of care)
- Has e1 of the following signs/symptoms that are attributable to severe or critical COVID-19:
- Shortness of breath at rest
- Respiratory rate e30 breaths per minute
- ... and 6 more (see full listing online)

Locations (218 total)

Cullman Clinical Trials (Site 3813), Cullman, Alabama, United States
Helios Clinical Research (Site 3826), Paradise Valley, Arizona, United States
Absolute Clinical Research (Site 3709), Phoenix, Arizona, United States
... and 215 more locations