Adaptive COVID-19 Treatment Trial 4 (ACTT-4)

Status: Recruiting

Eligibility Criteria

Sex: All
Age: 18 Years to 99 Years old
Healthy Volunteers: This study is NOT accepting healthy volunteers

Inclusion Criteria:
1. Hospitalized with symptoms suggestive of COVID-19. 2. Subject (or legally authorized representative) provides informed consent prior to initiation of any study procedures and understands and agrees to comply with planned study procedures. 3. Male or non-pregnant female adult ≥18 years of age at time of enrollment. 4. Illness of any duration and has laboratory-confirmed SARS-CoV-2 infection as determined by polymerase chain reaction (PCR) or other commercial or public health assay (e.g. NAAT, antigen test) in any respiratory specimen or saliva ≤14 days prior to randomization. 5. Within the 7 days prior to randomization requiring new use of supplemental oxygen (or increased oxygen requirement if on chronic oxygen) and requires at the time of randomization low or high flow oxygen devices or use of non-invasive mechanical ventilation (ordinal scale category 5 or 6). 6. Women of childbearing potential must agree to either abstinence or use at least one primary form of contraception not including hormonal contraception from the time of screening through Day 29. 7. Agrees not to participate in another blinded clinical trial (both pharmacologic and other types of interventions) for the treatment of COVID-19 through Day 29.

Exclusion Criteria:
1. Prior enrollment in ACTT-3 or ACTT-4. 2. On invasive mechanical ventilation at the time of randomization (ordinal scale category 7). 3. Anticipated discharge from the hospital or transfer to another hospital which is not a study site within 72 hours of randomization. 4. Positive test for influenza virus during the current illness (influenza testing is not required by protocol). 5. Subjects with a low glomerular filtration rate (eGFR), specifically: 1. Subjects with an eGFR 20-30 mL/min are excluded unless in the opinion of the PI, the potential benefit of participation outweighs the potential risk of study participation. 2. All subjects with an eGFR <20 mL/min (including hemodialysis and hemofiltration) are excluded. 6. Neutropenia (absolute neutrophil count <700 cells/microliter, 0.7 x 10^3/microliter). 7. Lymphopenia (absolute lymphocyte count <200 cells/microliter, 0.20 x 10^3/microliter). 8. Received five or more doses of remdesivir including the loading dose, outside of the study as treatment for COVID-19. 9. Pregnancy or breast feeding (lactating women who agree to discard breast milk from Day 1 until two weeks after the last study product is given are not excluded). 10. Allergy to any study medication. 11. Received convalescent plasma or intravenous immunoglobulin (IVig) for COVID-19, the current illness for which they are being enrolled. 12. Received any of the following in the two weeks prior to screening as treatment of COVID-19:
   • small molecule tyrosine kinase inhibitors (e.g. baricitinib, imatinib, gefitinib, acalabrutinib, etc.);
   • monoclonal antibodies targeting cytokines (e.g., TNF inhibitors, anti-interleukin-1 [IL-1], anti-IL-6 [tocilizumab or sarilumab], etc.);
   • monoclonal antibodies targeting T-cells or B-cells as treatment for COVID-19. 13. Use of probenecid that cannot be discontinued at study enrollment. 14. Received more than one dose of dexamethasone 6 mg or larger (or equivalent for other glucocorticoids) in the 7 days prior to time of randomization. Note: total daily dose equivalents include 40 mg prednisone, 32 mg methylprednisolone and 160 mg hydrocortisone. 15. Received >20 mg/day of prednisone (or equivalent for other glucocorticoids) for ≥14 consecutive days in the 4 weeks prior to screening. 16. Have diagnosis of current active or latent tuberculosis (TB), if known, treated for less than 4 weeks with appropriate therapy (by history only, no screening required). 17. Serious infection (besides COVID-19), immunosuppressive state, or immunosuppressive medications that in the opinion of the investigator could constitute a risk when taking baricitinib or dexamethasone. 18. Have received any live vaccine (that is, live attenuated) within 4 weeks before screening, or intend to receive a live vaccine (or live attenuated) during the study. Note: Use of non-live (inactivated) vaccinations is allowed for all subjects.

Conditions & Interventions

Interventions:
Drug: Baricitinib, Drug: Dexamethasone, Other: Placebo, Drug: Remdesivir

Conditions:
COVID-19

Keywords:
ACTT, Adaptive, COVID-19, Efficacy, Multicenter, novel coronavirus, Safety

More Information

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