ongoing trials - trial from other registries

A randomized, open-label, active controlled, parallel group, multicenter phase 3 study to evaluate the efficacy and tolerability of Bamlanivimab and Etesevimab, Casirivimab and Imdevimab, and Sotrovimab versus Standard of Care in patients with mild to moderate COVID-19 disease (AntiCov)

Code: EUCTR2021-004035-88 **Year:** 2021 **Date:** 2021 **Author:**

Study design (if review, criteria of inclusion for studies)

Controlled: Yes.1 Randomised: Yes.2 Open: Yes.3 Single blind: No.4 Double blind: No.5 Parallel group: Yes.6 Cross over: No

Participants

Principal inclusion criteria: Men or non-pregnant women 12 years of age at the time of randomization; currently not hospitalized; one or more mild or moderate COVID-19 symptoms such as fever, cough, sore throat, malaise, headache, muscle pain, gastrointestinal symptoms, or shortness of breath; sample collection for first positive SARS-CoV-2 viral infection

Interventions

E.2.1 Main objective of the trial: The primary objective of the study is: - To assess the efficacy of monoclonal antibodies (Bamlanivimab/Etesevimab, Casirivimab/Imdevimab, Sotrovimab) in patients with COVID-19 by looking at disease progression in terms of hospitalization in intensive care unit

Outcome measures

The primary endpoint of the study is: - Disease progression defined as: hospitalization in intensive care unit, oxygen desaturation 4% and peripheral oxygen saturation 92% during the follow-up period (30 days). Timepoint(s) of evaluation of this end point: Timepoint are reported within the endpoint list

https://www.clinicaltrialsregister.eu/ctr-search/trial/2021-004035-88/IT/

Keywords

Bamlanivimab; Casirivimab; Etesevimab; Imdevimab; Sotrovimab; Monoclonal Antibodies; pharmacological_intervention; COVID-19; infection; virus;