ForPatients
by Roche

Pneumonia por COVID-19

Um estudo para avaliar a eficácia e a segurança do tocilizumabe em participantes hospitalizados com pneumonia por COVID-19

A Study to Evaluate the Efficacy and Safety of Tocilizumab in Hospitalized Participants With COVID-19 Pneumonia

Trial Status	Trial Runs In	Trial Identifier
Concluído	6 Countries	NCT04372186 ML42528

As informações abaixo foram obtidas diretamente de sites de registro público, como ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com etc., e não foram editadas.

Official Title:

A Randomized, Double-Blind, Placebo-Controlled, Multicenter Study to Evaluate the Efficacy and Safety of Tocilizumab in Hospitalized Patients With COVID-19 Pneumonia

Trial Summary:

This study (EMPACTA) will a) evaluate the efficacy and safety of tocilizumab (TCZ) compared with a placebo in combination with standard of care (SOC) in hospitalized participants with COVID-19 pneumonia, and b) include an optional long-term extension for eligible participants to explore the long-term sequelae of resolved COVID-19 pneumonia.

Genentech, Inc.
Sponsor

Phase 3
Phase

NCT04372186 ML42528
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

Inclusion Criteria:

- Hospitalized
- COVID-19 pneumonia confirmed by a positive polymerase chain reaction (PCR) of any specimen and radiographic imaging
- SpO2 < 94% while on ambient air

Inclusion Criteria Specific to Long-Term Extension

- Participated in Study ML42528 (EMPACTA) (includes participants who completed or discontinued early from the main study)

Exclusion Criteria:

- Known severe allergic reactions to TCZ or other monoclonal antibodies
- Require continuous positive airway pressure (CPAP), bilevel positive airway pressure (BIPAP), or invasive mechanical ventilation
- Suspected active bacterial, fungal, viral, or other infection (besides COVID-19)
- In the opinion of the investigator, progression to death is imminent and inevitable within the next 24 hours, irrespective of the provision of treatments
- Immunocompromised (besides well-controlled HIV) or on immunosuppressive therapy (except for steroids for COVID), advanced cancer
- Have received oral anti-rejection or immunomodulatory drugs (including TCZ) within the past 3 months
- Participating in another interleukin (IL)-6 antagonist clinical trial or other drug clinical trials (participation in COVID-19 anti-viral trials may be permitted if approved by Medical Monitor)
- Alanine aminotransferase (ALT) or aspartate aminotransferase (AST) > 10 x upper limit of normal (ULN) detected within 24 hours at screening (according to local laboratory reference ranges)
- Absolute neutrophil count (ANC) < 1000/uL at screening (according to local laboratory reference ranges)
- Platelet count < 50,000/uL at screening (according to local laboratory reference ranges)
- Pregnant or breastfeeding, or positive pregnancy test in a pre-dose examination
- Treatment with an investigational drug within 5 half lives or 30 days (whichever is longer) of randomization (investigational COVID-19 antivirals may be permitted if approved by Medical Monitor)
- Any serious medical condition or abnormality of clinical laboratory tests that, in the investigator's judgment, precludes the patient's safe participation in and completion of the study
- Any history of Diverticulitis or GI perforation
- Use of systemic corticosteroids unless on a stable chronic dose