

Neumonía por COVID-19

**Un estudio para evaluar la eficacia y seguridad de Tocilizumab en participantes hospitalizados con neumonía por COVID-19**

**Trial Status**  
Terminado

**Trial Runs In**  
6 Countries

**Trial Identifier**  
NCT04372186 ML42528

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La información se obtuvo directamente de sitios web de registros públicos, como ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., y no se ha editado.

**Official Title:**

ESTUDIO ALEATORIZADO, DOBLE CIEGO, CONTROLADO CON PLACEBO, MULTICÉNTRICO PARA EVALUAR LA EFICACIA Y SEGURIDAD DE TOCILIZUMAB EN PACIENTES HOSPITALIZADOS CON NEUMONÍA POR COVID-19

**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

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**NCT04372186 ML42528**  
Trial Identifiers

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**Eligibility Criteria:**

**Gender**  
All

**Age**  
#18 Years

**Healthy Volunteers**  
No

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**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

# ForPatients

*by Roche*

## 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