ForPatients
by Roche

COVID-19 Pneumonia

A Study to Investigate Intravenous Tocilizumab in Participants With Moderate to Severe COVID-19 Pneumonia

Trial Status	Trial Runs In	Trial Identifier
Completed	1 Country	NCT04363736 CA42481

The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

Official Title:

A Phase-II, Open-Label, Randomized, Multicenter Study to Investigate the Pharmacodynamics, Pharmacokinetics, Safety, and Efficacy of 8 mg/kg or 4mg/kg Intravenous Tocilizumab in Patients With Moderate to Severe COVID-19 Pneumonia

Trial Summary:

This study will assess the pharmacodynamics, pharmacokinetics, safety and efficacy of two different doses of tocilizumab (TCZ) in combination with standard-of-care (SOC) in hospitalized adult participants with moderate to severe COVID-19 pneumonia.

Hoffmann-La Roche
Sponsor

Phase 2
Phase

NCT04363736 CA42481
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

Inclusion Criteria:

- Hospitalization with COVID-19 pneumonia confirmed by a positive polymerase chain reaction (PCR) of any specimen [e.g., respiratory, blood, urine, stool, and other bodily fluids]) and evidence of pneumonia on chest X-ray or computed tomography scan
- For severe patients, SpO2 </= 93% or PaO2/FiO2 < 300 mmHg. If a participant is on supplemental oxygen with SpO2 > 93%, but desaturation </= to 93% on lower supplemental oxygen or ambient air is documented during screening, the inclusion criterion is met

- For moderate patients (those who do not qualify as severe based oxygen requirements), CRP > 2 x upper limit of normal (ULN) is required
- For women of childbearing potential: agreement to remain abstinent (refrain from heterosexual intercourse) or use contraception, as defined by the protocol
- For men: agreement to remain abstinent (refrain from heterosexual intercourse) or use a condom, and agreement to refrain from donating sperm, as defined by the protocol

Exclusion Criteria:

- Known severe allergic reactions to TCZ or other monoclonal antibodies
- Active tuberculosis (TB) infection
- Suspected active bacterial, fungal, viral, or other infection (besides SARS-CoV-2)
- Participants who are on a mechanical ventilator > 24 hours or extracorporeal membrane oxygenation (ECMO), in shock, or combination thereof with other organ failure requiring treatment in an ICU
- In the opinion of the investigator, progression to death is imminent and inevitable within the next 24 hours, irrespective of the provision of treatments
- Receipt of oral anti-rejection or immunomodulatory drugs (including TCZ) within the past 3 months
- Alanine aminotransferase (ALT) or aspartate aminotransferase (AST) > 10 x ULN detected within 24 hours at screening or at baseline (according to local laboratory reference ranges)
- Absolute neutrophil count (ANC) < 1000/uL at screening and baseline (according to local laboratory reference ranges)
- Platelet count < 50,000/uL at screening and baseline (according to local laboratory reference ranges)
- Pregnancy or breastfeeding, or positive pregnancy test at a predose examination
- Treatment with an investigational drug within 5 drug-elimination half-lives or 30 days (whichever is longer) of randomization