ForPatients
by Roche

COVID-19 Pneumonia COVID-19

A clinical trial to look at the safety and activity of tocilizumab in children and adolescents with COVID-19

A Study Evaluating Tocilizumab in Pediatric Patients Hospitalized With COVID-19

Trial Status	Trial Runs In	Trial Identifier
Completed	11 Countries	NCT05164133 WA43811

The source of the below information is the publicly available website ClinicalTrials.gov. It has been summarised and edited into simpler language.

Trial Summary:

This is a single-arm, open-label study to assess the pharmacokinetics, pharmacodynamics, safety, and exploratory efficacy of tocilizumab (TCZ) for the treatment of pediatric patients from birth to less than 18 years old hospitalized with COVID-19 and who are receiving systemic corticosteroids and require supplemental oxygen or mechanical ventilation.

Hoffmann-La Roche Sponsor	**Phase 1** Phase

NCT05164133 WA43811
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	<= 17 Years	No

Why is the Gypsophila clinical trial needed?

Coronavirus disease 2019 (COVID-19) is an infectious disease caused by a virus. Although an increasing number of treatments are becoming available for adults, there are very limited treatment options developed for children, and vaccines have not yet been approved for use in children of all age groups (at the time the study was designed). Therefore, there is an urgent medical need for effective therapies for children and adolescents who are very unwell with COVID-19 and which requires them to be cared for in a hospital.

Tocilizumab is a drug that has shown to be effective in adults hospitalised with COVID-19. While doctors know a lot about tocilizumab, the side effects and effectiveness of tocilizumab when used in children and adolescents with COVID-19 are unknown.

How does the Gypsophila clinical trial work?

This clinical trial is recruiting children and adolescents who have been hospitalised with COVID-19 and need treatment with additional oxygen. Participants can take part if they are under 18 years old and are receiving corticosteroids given systemically (e.g. by mouth or as an injection).

The purpose of this clinical trial is to test the safety of tocilizumab in children and adolescents with COVID-19, given as an infusion into the vein, and to understand the way the body processes the drug. This trial will also start to look at how effective tocilizumab is for the treatment of COVID-19 in children and adolescents.

Participants will be given the clinical trial treatment i.e. tocilizumab, once on Day 1 of the trial. Participants may receive one additional dose of tocilizumab 8#24 hours after the first dose, if there is no improvement in or worsening of COVID-19 symptoms. Participants will be seen by the clinical trial doctor every day for as long as the participant is in hospital. After the participant is discharged from hospital, they may be asked to return occasionally for additional tests. These visits will include checks to see how the participant is responding to the treatment and any side effects they may be having. These may include:

- Blood and urine sample collection
- Chest X-ray or scan
- Electrocardiogram to measure the electrical activity of the heart
- Heart rate, blood pressure, breathing rate, and oxygen level in the blood
- Side effects

Participants' total time in the clinical trial will be around 60 days. Participants are free to stop trial treatment and leave the clinical trial at any time.

What are the main endpoints of the Gypsophila clinical trial?

The main clinical trial endpoints (the main results that are measured in the trial) are: to find out the levels of tocilizumab present in the participant’s blood over 28 days, and if anything affects the blood levels of the drug.

The other clinical trial endpoints include: how well a participant responds to tocilizumab treatment over 60 days; how tocilizumab affects a participant's immune system; the number and seriousness of any side effects experienced by the participant over 60 days, and the relationship between the dose of tocilizumab and safety and other measures.

Who can take part in this clinical trial?

People can take part in this trial if they are under 18 years old, have been hospitalised with

COVID-19, are receiving systemic corticosteroids, and need treatment with additional oxygen.

People may not be able to take part in this trial if they have recently received certain other treatments, are pregnant or planning to become pregnant, are breastfeeding, or have a known history of severe allergies to tocilizumab or similar drugs, or have certain other medical conditions.

What treatment will participants be given in this clinical trial?

This is an open-label trial which means everyone involved, including the participants and the doctors, know which medicine is being used. Everyone who joins this clinical trial will be given tocilizumab as an injection into the vein:

- Participants will receive a single injection of tocilizumab on Day 1 of the trial; the dose of tocilizumab will be based on body weight
- Participants may receive one additional injection of tocilizumab 8#24 hours after the first dose, if there is no improvement in or worsening of COVID-19 symptoms.

Are there any risks or benefits in taking part in this clinical trial?

The safety or effectiveness of the experimental treatment or use may not be fully known at the time of the trial. Most trials involve some risks to the participant, although it may not be greater than the risks related to routine medical care or the natural progression of the health condition. Potential participants will be told about any risks and benefits of taking part in the clinical trial, as well as any additional procedures, tests, or assessments they will be asked to undergo. These will all be described in an informed consent document (a document that provides people with the information they need to make a decision to volunteer for a clinical trial). A potential participant should also discuss these with members of the research team and with their usual healthcare provider. Anyone interested in taking part in a clinical trial should know as much as possible about the trial and feel comfortable asking the research team any questions about the trial.

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Risks associated with the clinical trial drugs

Participants may have side effects (an unwanted effect of a drug or medical treatment) from the drugs used in this clinical trial. Side effects can be mild to severe and even life-threatening, and can vary from person to person.

Tocilizumab: Potential participants will be told about the known side effects of tocilizumab, and where relevant, also potential side effects based on human and laboratory studies or knowledge of similar drugs.

Tocilizumab will be given by intravenous injection (involves inserting a needle into a vein to allow the medicine to enter the bloodstream right away). Participants will be told about any known side effects of intravenous administration.

Potential benefits associated with the Gypsophila clinical trial

Participants' health may or may not improve from participation in the clinical trial, but the information that is collected may help other people who have a similar medical condition in the future.

For more information about this clinical trial see the **For Expert** tab on the specific ForPatients page or follow this link to ClinicalTrials.gov: https://clinicaltrials.gov/ct2/show/NCT05164133