ForPatients
by Roche

COVID-19COVID-19 Pneumonia

A clinical trial to compare the safety and effectiveness of AT-527 with placebo in people with mild or moderate COVID-19

Study to Evaluate the Effects of RO7496998 (AT-527) in Non-Hospitalized Adult and Adolescent Participants With Mild or Moderate COVID-19

Trial Status	Trial Runs In	Trial Identifier
Terminated	12 Countries	NCT04889040 2020-005759-18 CV43043

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 Multicenter, Phase III Randomized, Double-Blind, Placebo-Controlled, Outpatient Study to Evaluate the Efficacy, Safety, Antiviral Activity of RO7496998 (AT-527) in Patients With Mild or Moderate COVID-19

Trial Summary:

This study will evaluate the efficacy, safety, antiviral activity, and pharmacokinetics of study drug RO7496998 (AT-527) compared to placebo in non-hospitalized adult and adolescent participants with mild to moderate coronavirus disease 2019 (COVID-19) in the outpatient setting.

Hoffmann-La Roche Sponsor	**Phase 3** Phase

NCT04889040 2020-005759-18 CV43043
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#12 Years	No

How does the CV43043 clinical trial work?

This clinical trial is recruiting people who have tested positive for the viral infection causing COVID-19. In order to take part, patients must have mild to moderate COVID-19 symptoms but must not have severe illness that needs to be treated in hospital.

The purpose of this clinical trial is to compare the effects, good or bad, of AT-527 against placebo in patients with mild or moderate COVID-19. If you take part in this clinical trial, you will receive either AT-527 (the active medicine) or placebo (looks like AT-527 but does not contain any active ingredients).

How do I take part in this clinical trial?

To be able to take part in this clinical trial, you must be at least 12 years old and have received a positive test result for COVID-19 no more than **three days before screening**. You must also have mild or moderate COVID-19 symptoms that started no more than **five days before the first dose** of study treatment.

You must not have severe illness with COVID-19 that needs to be treated in hospital at the start of the clinical trial. You may also not be able to take part in this clinical trial if you have certain other medical conditions or if you have previously received certain medications. You must not be pregnant, breastfeeding, or intending to become pregnant during or soon after the clinical trial.

If you think this clinical trial may be suitable for you and would like to take part, please talk to your doctor. If your doctor thinks that you might be able to take part in this clinical trial, he/she may refer you to the closest clinical trial doctor. The clinical trial doctor will confirm if you have mild or moderate COVID-19 disease and if you are suitable for this clinical trial based on your medical history. They will give you all the information you need to make your decision about taking part in the clinical trial. You can also find the clinical trial locations on this page.

You will have some further tests to make sure you will be able to take the treatments given in this clinical trial. Some of these tests or procedures may be part of the regular medical care for COVID-19. They may be done even if you do not take part in the clinical trial. If you have had some of the tests recently, they may not need to be done again.

Before starting the clinical trial, you will be told about any risks and benefits of taking part in the trial. You will also be told what other options are available so that you may decide if you still want to take part.

While taking part in the clinical trial, women (if you are not currently pregnant but can become pregnant) will need to either not have heterosexual intercourse or take contraceptive medication for safety reasons. Hormonal contraceptive methods must be supplemented by a barrier method.

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What treatment will I be given if I join this clinical trial?

Everyone who joins this clinical trial will be split into two groups randomly and given either:

- AT-527 as two tablets twice a day for five days
- Placebo as two tablets twice a day for five days

You will have a 2 in 3 chance of being placed in the AT-527 group, and a 1 in 3 chance of being placed in the placebo group.

This is a 'placebo-controlled' clinical trial, which means that one of the groups will be given medicine with no active ingredients (also known as a 'placebo'). A placebo is used to show that the doctor or the patients do not sway the results of the clinical trial.

Neither you nor your clinical trial doctor can choose or know the group (AT-527 or placebo) you are in. However, your clinical trial doctor can find out which group you are in if your safety is at risk.

How often will I be seen in follow-up appointments and for how long?

You will be given the clinical trial treatment AT-527 or placebo for five days. You are free to stop this treatment at any time. For the first two weeks of the clinical trial, you will still be seen regularly by the clinical trial doctor, so that he/she can check how you are responding and can collect nasopharyngeal swabs (from the back of the nose and throat), saliva, and blood samples. Someone from the clinical trial team may visit you in your home if you are unable to attend hospital appointments.

All patients will be asked to complete a diary of their symptoms throughout the clinical trial and will receive follow-up phone calls approximately 21, 28 and 33 days after the first dose of treatment, so that the clinical trial team can collect final information. Your total time in the clinical trial will be roughly 33 days.

What happens if I am unable to take part in this clinical trial?

If this clinical trial is not suitable for you, you will not be able to take part. Your doctor will suggest other clinical trials that you may be able to take part in or other treatments that you can be given. You will not lose access to any of your regular care.

For more information about this clinical trial see the **For Expert** tab on the specific ForPatient page or follow this link to ClinicalTrials.gov

Trial-identifier: NCT04889040

Inclusion Criteria:

- Positive SARS-CoV-2 diagnostic test (RT-PCR or validated rapid antigen test) #72 hours prior to randomization
- At least three of the following symptoms of at least moderate (score #2 as per COVID-19 Symptom Diary) intensity: nasal congestion or runny nose, sore throat, cough, shortness of breath, muscle or body aches, fatigue, headache, chills or sweats, feeling hot or feverish, nausea, vomiting, or diarrhea.
- Has symptoms consistent with mild or moderate COVID-19, as determined by the investigator, with onset #5 days before dosing on Day 1

Exclusion Criteria:

- Clinical signs indicative of COVID-19 illness requiring hospitalization
- Admitted to a hospital prior to randomization or is hospitalized (inpatient) at randomization due to COVID-19
- In the opinion of the investigator, is likely to experience imminent deterioration and require hospitalization
- Treatment with an investigational drug within 5 half-lives or 3 months (whichever is longer) of randomization
- Treatment with a COVID-19 therapeutic agent including, but not limited to, other direct or indirect acting antivirals against SARS-CoV-2 (such as remdesivir or favipiravir), systemic or inhaled steroids (such as dexamethasone or inhaled budesonide), colchicine, ivermectin, interferons, convalescent plasma, monoclonal antibodies against SARS CoV-2 or interleukin 6 (IL-6), intravenous immunoglobulin or other EUA-approved treatments within 3 months or less than 5 drug elimination half-lives (whichever is longer) prior to the screening visit
- Concomitant use of P-glycoprotein inhibitors or inducers listed as prohibited therapy in the protocol
- Known allergy or hypersensitivity to components of study drug
- Abnormal laboratory test results at screening
- Requirement of any prohibited medications during the study
- Other known active viral or bacterial infection at the time of screening, such as influenza
- Any clinically significant medical condition or laboratory abnormality that, in the opinion of the investigator, could jeopardize the safety of the patient or affect patient compliance or safety/efficacy observations during the study
- COVID-19 vaccination within # 40-days prior to enrollment (second dose if applicable)