ForPatients
by Roche

COVID-19 PneumoniaCOVID-19

Study to Evaluate the Effects of AT-527 in Non-Hospitalized Adult Patients With Mild or Moderate COVID-19

Trial Status	Trial Runs In	Trial Identifier
Completed	6 Countries	NCT04709835 WV43042

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 Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Antiviral Activity, Safety, Pharmacokinetics, and Efficacy of RO7496998 (AT-527) in Non-Hospitalized Adult Patients With Mild or Moderate COVID-19

Trial Summary:

This randomized study evaluates the antiviral activity, safety, efficacy and pharmacokinetics of AT-527 versus a placebo in participants with mild or moderate coronavirus disease (COVID-19) who are not hospitalized.

Hoffmann-La Roche	Phase 2
Sponsor	Phase

NCT04709835 WV43042
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

How does the MOONSONG (WV43042) clinical trial work? This clinical trial is recruiting people who have tested positive for the viral infection COVID-19. In order to take part, patients must have mild or 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 or a placebo.

How do I take part in this clinical trial? To be able to take part in this clinical trial, you must be 18–64 years old and have been diagnosed with COVID-19 at the time of screening. You must also have mild or moderate COVID-19 symptoms that started no more than 5 days before the first dose of study treatment.

You must not have COVID-19 symptoms that need to be treated in hospital, have a condition that may increase your risk for developing severe COVID-19 or have previously received treatment for COVID-19. Current or former heavy smokers will also not be able to take part in this trial. If you have a history of some other conditions, you may not be able to take part in this 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. 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 a further COVID-19 test to confirm you definitely have COVID-19 before you take part in the study. During the study you will have some further tests to monitor your health and to understand the effects of the study treatment on your body.

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, both men and women (if you are not currently pregnant but can become pregnant) will need to either not have heterosexual intercourse or use an effective contraception method, as the effect of the study treatment on a developing baby is currently unknown.

What treatment will I be given if I join this clinical trial? Everyone who joins this clinical trial will be enrolled into one of five different groups (A–E), based on when they join the study. In each group, everyone will be split into two treatment arms randomly (like flipping a coin) and given either:

- AT-527 as a pill for five days
- OR placebo as a pill for five days

If you are enrolled into Group A, you will have a 1 in 2 chance of being placed in the AT-527 treatment arm or the placebo treatment arm. If you are enrolled into Groups B, C,

D or E, you will have a 3 in 4 chance of being placed in the AT-527 treatment arm and a 1 in 4 chance of being placed in the placebo treatment arm.

- Group A will be given AT-527 or placebo twice per day for five days
- The dose for Groups B, C, D or E will be decided after results from Group A have been reviewed

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'). Comparing the effects of a study treatment with a placebo helps to show that the study treatment is effective for treating a disease.

Neither you nor your clinical trial doctor can choose or know the treatment arm (AT-527 or placebo) you are in. However, your clinical trial doctor can find out which arm 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 5 days.

- If you are in Group A, you will be treated as an outpatient and can take the treatment at home
- If you are in Group B, C, D or E, you will be treated in a clinic and will stay there as a resident for 14 days

You are free to stop this treatment at any time. While being given treatment, you will still be seen regularly by a member of the clinical trial team.

- If you are in Group A, you will be seen every other day at home for the first 7 days so that the clinical trial team can check how you are responding and collect nasal swabs and blood samples
- If you are in Group B, C, D or E, you will be closely monitored throughout the 14 days of your stay so that the clinical trial team can make detailed observations about how your body responds to the treatment

All patients will be asked to complete a diary of their symptoms throughout the study. All patients will receive a follow-up phone call roughly 33 days after the first dose of study treatment, so that the clinical trial team can collect final information.

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.

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For more information about this clinical trial see the For Expert tab on the specific ForPatient page or follow this link to ClinicalTrials.gov https://clinicaltrials.gov/ct2/show/NCT04709835?term=WV43042&draw=2&rank=1

Trial-identifier: NCT04709835

Inclusion Criteria:

- Positive SARS-CoV-2 diagnostic test (RT-PCR or rapid antigen test)at screening
- Has symptoms consistent with mild or moderate COVID-19, as determined by the investigator, with onset #5 days prior to randomization

Exclusion Criteria:

- Clinical signs indicative of COVID-19 illness requiring hospitalization, defined as any of the following: shortness of breath at rest, respiratory rate #30, heart rate #125, peripheral capillary oxygen saturation #93% on room air
- Treatment with a therapeutic agent against SARS-CoV-2 including, but not limited to, other direct acting antivirals, convalescent plasma, monoclonal antibodies against SARS CoV-2, or intravenous immunoglobulin within 3 months or less than 5 drug elimination half-lives (whichever is longer) prior to screening
- Requirement, in the opinion of the investigator, for any of the prohibited medications during the study
- Use of hydroxychloroquine or amiodarone within 3 months of screening
- Pregnant or breastfeeding, or intending to become pregnant during the study or within 30 days after the final dose of AT-527. Women of childbearing potential must have a negative urine pregnancy test result at screening
- Abnormal laboratory test results at screening
- Clinically significant abnormal ECG, as determined by the Investigator, at screening
- Planned procedure or surgery during the study
- Known allergy or hypersensitivity to study drug or drug product excipients
- Substance abuse, as determined by the investigator, within 12 months prior to screening
- Poor peripheral venous access
- Malabsorption syndrome or other condition that would interfere with enteral absorption
- Any clinically significant history of epistaxis within the last 3 months and/or history of being hospitalized due to epistaxis of any previous occasion
- History of anaphylaxis
- Any uncontrolled serious medical condition or other clinically significant abnormality in clinical laboratory tests that, in the investigator's judgment, precludes the patient's safe participation in and completion of the study