



PLAIN LANGUAGE SUMMARY OF CLINICAL STUDY RESULTS

Study Sponsor: Gilead Sciences

Gilead Study Number: GS-US-685-6819

Date of Study: October 2024 to June 2025 (the study closed earlier than planned)



Plain Language Study Title: Study of Obeldesivir to Treat Nonhospitalized Adults With Acute Respiratory Syncytial Virus (RSV) Infection

Date of this Plain Language Summary: July 2026

The information in this summary does not include any information available after this date.

Thank you

Thank you to the participants who contributed to the clinical study for **obeldesivir**, also known as **GS-5245**.



Gilead Sciences sponsored this study. This summary is prepared for study participants and the general public.

If you participated in the study and have questions about the results, please speak with a doctor or staff member at the study site.

Always talk to a doctor or healthcare provider before making any treatment changes.

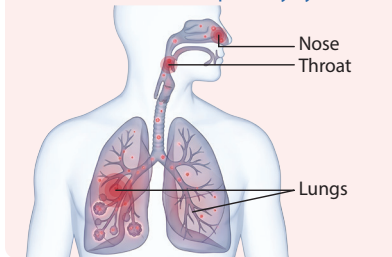
This document is a short summary of this study written for a general audience. Links to scientific summaries of this study can be found at the end of this document.

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General information about the study

What is Respiratory Syncytial Virus Infection?

RSV affects the respiratory system



Respiratory syncytial virus (RSV) is a common virus that affects the lungs and other parts of the respiratory system (parts of the body that help us breathe). Young children, elderly people, and people who already have breathing or lung problems are at highest risk of getting very sick from RSV infection, but people of any age can get sick from RSV infection.

Common symptoms of RSV infection include high fever, cough, sore throat, runny nose, headache, and feeling tired.

Currently, there is no specific treatment for RSV infection. Doctors treat severe RSV infection with supportive care. This may include fluids given through a drip directly into the blood to keep the body hydrated and extra oxygen to help with breathing. Researchers wanted to find a medicine that people can take by mouth to help them recover faster and avoid going to the hospital.

This study tested a study drug called obeldesivir, which is taken by mouth as a pill. Researchers wanted to find out if it could treat people with a recent RSV infection who did not need hospital care.

This was a Phase 2 clinical study. This means researchers tested obeldesivir in about 150 adults with RSV infection.



What was the purpose of the study?

The purpose of this study was to learn how well treatment with obeldesivir works and how safe it is in adults with RSV infection.

The main questions the researchers wanted to answer in this study were:

- How long did it take for participants' RSV symptoms to get better after treatment?
- How many participants had **unwanted medical events**, **serious unwanted medical events**, or **stopped treatment** because of these events?
- How many participants had **abnormal** changes in their laboratory test results during the study?

Researchers also wanted to know if there were any **side effects** that the participants had during the study.



An **unwanted medical event** is any unwanted sign or symptom that participants may have during the study. An unwanted medical event is considered **“serious”** if it:

- results in death
- is life-threatening
- is considered by the study doctor to be medically important
- causes lasting problems
- requires hospital care
- causes a birth defect

Abnormal changes in laboratory test results mean results that are outside the normal (expected) range.

An unwanted medical event may or may not be caused by the study treatment. **Side effects** are unwanted medical events that the study doctors thought **might be caused by the study drug**.



Who took part in the study?

The study enrolled **150** adult participants with RSV infection from the **United States**.

People could take part in the study if they:



Were at least 18 years of age



Had RSV infection confirmed by a suitable test, within 3 days before starting the study



Showed symptoms of RSV infection, within 3 days before starting the study, however, were not hospitalized



Had one of the risks of getting severe RSV infection like, age: more than 60 years, other lung diseases like asthma

The 150 study participants were between the ages of **18** and **88** years.

The race of participants is shown below (number of participants (%)).

White	130 (87%)
Black or African American	16 (11%)
Asian	3 (2%)
American Indian or Alaska Native	1 (below 1%)

The ethnicity of participants is shown below (number of participants (%)).

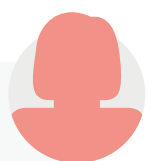
Hispanic or Latino	108 (72%)
Not Hispanic or Latino	41 (27%)
Not Collected	1 (below 1%)

The sex of participants is shown below (number of participants (%)).



Male

66 participants (44%)



Female

84 participants (56%)



What happened during the study?

Before the study began, adults were screened to see if they were a good fit. Screening included physical exams, a review of health, and medication history. Study doctors performed tests to confirm RSV infection.

This was a **randomized**, **double-blind**, and **placebo-controlled** study.



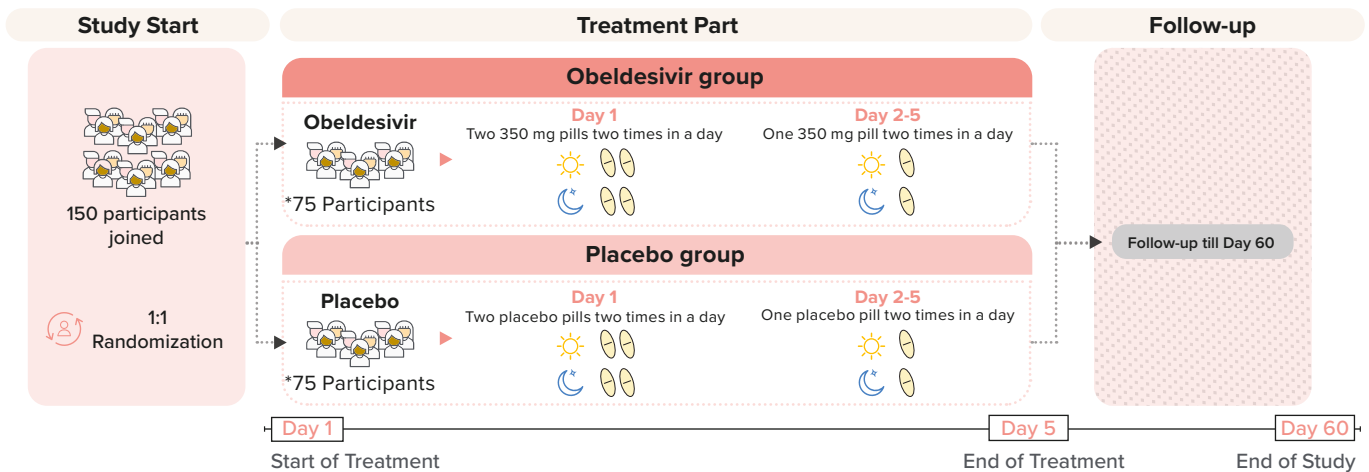
Randomized means the researchers used a computer program to assign participants into treatment groups by chance. This helped make sure the treatments were assigned fairly. In this study, equal numbers of participants received either obeldesivir or a placebo (1:1 randomization).

Double-blind means that none of the participants, doctors or other study staff knew what treatment each participant received. This was done to make sure that the study results were not influenced in any way. Some sponsor staff knew which treatment each participant received, to help monitor participants' safety throughout the study.

Placebo-controlled means that researchers compared the treatment with a placebo to see how well it worked and how safe it was. A **placebo** looks like the treatment (in this study, the obeldesivir pill) but does not have any active medicine in it.

Participants took obeldesivir or matching placebo pills for 5 days. On Day 1, they took 2 pills (350 milligrams (mg) each, 700 mg total) in the morning and 2 pills (350 mg each, 700 mg total) in the evening. From Day 2 to Day 5, they took 1 pill (350 mg) in the morning and 1 pill (350 mg) in the evening.

The graphics below show the treatment plan.



* One out of 75 participants in both the obeldesivir group and the placebo group left the study before starting treatment.

The researchers monitored participants for safety throughout the study. They also gave participants a questionnaire to fill every day from Day 1 to Day 15 to describe the severity of their symptoms. Out of 150 participants who joined the study, 148 received obeldesivir or placebo. Of the 148 participants, 146 completed the study. Two participants in the placebo group chose to leave the study before it ended.

The sponsor decided to close the study earlier than planned. There were no safety concerns.

What were the results of the study?

This is a summary of the main results from this study. The individual results of each participant might be different and are not mentioned in this summary. A detailed presentation of the results can be found on the websites listed at the end of this summary.

How long did it take for participants' RSV symptoms to get better after treatment?

In total, 150 participants started the study. The results below only include 133 participants who took at least one dose of obeldesivir or placebo, and had confirmed RSV infection. This included 67 participants in obeldesivir and 66 in placebo group.

The researchers wanted to find out how long it took for RSV symptoms to improve. They checked the answers given by the participants in the questionnaire to understand the severity of participants' symptoms. They calculated the average number of days the participants' symptoms took to improve in both the groups.

Researchers found that RSV symptoms improved in a similar amount of time in both groups. On an average, symptoms improved in 3.2 days with obeldesivir and 3.9 days with placebo.

This small difference may have happened by chance, so **obeldesivir did not show a clear benefit over placebo** for this outcome.

Obeldesivir Group
(67 participants)

3.2
Days

Placebo Group
(66 participants)

3.9
Days

How many participants had unwanted medical events, serious unwanted medical events, or stopped treatment because of these events?

The researchers kept track of any unwanted medical events that participants had during the study. They assessed how many of them were serious events. They also tracked how many participants stopped treatment due to unwanted medical events during the study. The results below include all 148 participants who took either obeldesivir or placebo.

The table below shows how many participants had any unwanted medical events, serious events, and how many participants stopped treatment due to these events during the study.

	Obeldesivir Group 74 participants	Placebo Group 74 participants	Total 148 participants
	Number of participants (%)		
How many participants had any unwanted medical events?	10 (14%)	12 (16%)	22 (15%)
How many participants had any serious unwanted medical events ?	0	1 (1%)	1 (below 1%)
How many participants stopped treatment due to unwanted medical events?	0	1 (1%)	1 (below 1%)

No participant in the obeldesivir group had a serious unwanted medical event. One participant in the placebo group had a serious unwanted medical event of lung infection (pneumonia).

No participant in the obeldesivir group stopped treatment due to unwanted medical events. One participant in the placebo group had unwanted medical events of bloating (abdominal distension), feeling sick to the stomach (nausea), chills, pain, and headache. They stopped the placebo treatment due to these medical events.

How many participants had abnormal changes in their laboratory test results during the study?

Laboratory tests were done before and after the study drugs were given to check whether any values changed to outside the normal range (abnormal changes).

The table below shows how many participants had abnormal changes in laboratory test results during the study.

Abnormal Changes in Laboratory Test Results			
	Obeldesivir Group 74 participants	Placebo Group 74 participants	Total 148 participants
	Number of participants (%)		
How many participants had any abnormal changes in laboratory test results?	44 (60%)	42 (58%)	86 (59%)

A similar number of participants in the obeldesivir and placebo groups had abnormal changes in laboratory test results. Most of these changes were mild to moderate. More severe changes were uncommon and similar in both groups.

Overall, participants with RSV infection found obeldesivir to be safe and well-tolerated.



What side effects did participants have during the study?

The researchers also checked if participants had any side effects during the study. Side effects are unwanted medical events that the study doctors thought might be caused by the study drug. The results from several studies are usually needed to help decide if a study drug actually causes a side effect.

The table below shows how many participants had side effects during the study.

Overall Side Effects			
	Obeldesivir Group 74 participants	Placebo Group 74 participants	Total 148 participants
	Number of participants (%)		
How many participants had any side effects?	4 (5%)	1 (1%)	5 (3%)

All the side effects seen in this study were not serious (non-serious) in nature and did not meet the definition of serious side effects mentioned in this summary.

None of the participants died or stopped taking study drug due to any side effects.

The table below lists all the non-serious side effects that occurred in the study participants.

Non-serious Side Effects			
	Obeldesivir Group 74 participants	Placebo Group 74 participants	Total 148 participants
	Number of participants (%)		
Feeling sick to the stomach (Nausea)	1 (1%)	1 (1%)	2 (1%)
Swollen belly or feeling full (Abdominal distension)	0	1 (1%)	1 (below 1%)
A feeling of being cold without an apparent cause (Chills)	0	1 (1%)	1 (below 1%)
An unusual amount of creatinine removed from the blood by the kidney possibly due to kidney problems (Creatinine renal clearance abnormal)	1 (1%)	0	1 (below 1%)
Frequent loose watery stools (Diarrhea)	1 (1%)	0	1 (below 1%)
Headache	0	1 (1%)	1 (below 1%)
Pain	0	1 (1%)	1 (below 1%)
Higher than normal number of platelets in blood (Thrombocytosis)	1 (1%)	0	1 (below 1%)

? How has this study helped researchers?

The researchers learned how well the treatment with obeldesivir worked and how safe it was in people with RSV infection.

The results from several studies are needed to help decide which treatments work and are safe. This summary shows only the main results from this one study. Other studies may provide new information or different results.

Gilead Sciences may have further studies with obeldesivir.

Where can I learn more about this study?

You can find more information about this study on the website listed below.

Organization (Website)	Study Identifier
United States National Institutes of Health (NIH) www.clinicaltrials.gov	ClinicalTrials.gov Number: NCT06585150
Gilead Website www.gileadclinicaltrials.com	GS-US-685-6819

Please note that information on these websites may be presented in a different way from this summary.

Full Study Title: A Phase 2 Randomized, Placebo-controlled Study of the Safety and Efficacy of Obeldesivir to Treat Nonhospitalized Adults With Acute Respiratory Syncytial Virus (RSV) Infection

To learn more about clinical trials in general,
please visit this [page](#) on www.clinicaltrials.gov website

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Clinical study participants belong to a large community of people who take part in clinical research around the world. They help researchers answer important health questions and find medical treatments for patients.

