
Study Sponsor: UCB Biopharma SRL

Treatment Studied: Alprazolam

Protocol Number: UP0104

Short Study Title: A study to learn how much alprazolam gets into the bodies of healthy participants when it is inhaled by mouth as a mist compared to when it is swallowed as a tablet.

Thank you

UCB thanks all the participants of this study. All the participants helped the researchers learn more about how alprazolam acts in the blood of healthy participants.

This is a summary of the main results of this study. An independent, non-profit organization helped prepare this summary of the study results, which included feedback from patients.

We think it is important to share the results with the participants and the public. We hope this summary helps the participants understand their important role in medical research.

The purpose of this summary is only to share information. If you need medical advice, please contact your doctor. If you participated in this study and have questions about the results, please speak with study staff.

Overview of this study



Why was the research needed?

Researchers are looking for a different way to treat epilepsy. Before a treatment is available for all patients, researchers do clinical studies to find out how the treatment works and how safe it is.



What treatment did the participants take?

The participants in this study took alprazolam. They took the study treatment in 2 different ways: by breathing it in through the mouth as a mist (inhaled) and by swallowing it as a tablet.



What were the results of this study?

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

- **Was the amount of alprazolam that got into the participants' blood different when it was inhaled by mouth as a mist compared to when it was swallowed as a tablet?**

Yes. The average **total** amount of alprazolam in the blood was around **15% lower when it was inhaled** by mouth compared to when it was swallowed as a tablet.

The average **highest** amount of alprazolam in the blood was around **43% higher when it was inhaled** by mouth compared to when it was swallowed as a tablet.

- **What medical problems did the study doctors report as possibly related to the study treatments?**

There were **23.8%** of participants who had medical problems that the study doctors reported as possibly being related to the study treatment. This was **5 out of 21** participants.

The most common medical problem that the study doctors reported as possibly being related to the study treatment was **decrease in blood oxygen levels**.

More details about the results of this study are included later in this summary.



Where can I learn more about this study?

You can find more information about this study on the website listed on the last page. When a full report of the study results is available, it also can be found on this website.

Why was the research needed?

The researchers in this study wanted to learn how much alprazolam got into the bodies of healthy participants when it was inhaled by mouth as a mist compared to when it was swallowed as a tablet. They also wanted to learn if the participants had any medical problems during the study. A “healthy participant” is someone who does not have the condition the treatment is trying to treat or other serious health conditions. This information is important to know before additional studies can be done that help find out if inhaled alprazolam can improve the health of people living with epilepsy.

Researchers are studying alprazolam to see if it can be used to treat seizures caused by epilepsy, which is a brain disorder. The symptoms of seizures can be different for each person but often include uncontrollable shaking and loss of consciousness.

Alprazolam taken as a **tablet** by mouth has been studied and approved to help treat anxiety and panic attacks. In this study, researchers wanted to use a device that changes alprazolam to a mist, which can then be **inhaled** by a person. This way, the drug may reach the blood faster and act quicker in the body.

In this study, the researchers wanted to see if similar amounts of alprazolam entered the body when it was inhaled by mouth as a mist compared to when it was swallowed as a tablet.

What were the main questions studied?

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

- Was the amount of alprazolam that got into the participants’ blood different when it was inhaled by mouth as a mist compared to when it was swallowed as a tablet?
- What medical problems did the study doctors report as possibly related to the study treatments?

Who participated in the study?

There were 21 healthy males and females who participated in this study. They were 23 to 55 years old when they joined.

The study included participants from the United States.

In this study, the researchers planned to include healthy participants who had not smoked in the 6 months before joining the study.

Each participant was in the study for up to 7 weeks, but the whole study lasted for about 2 months. The study started in December 2022 and ended in February 2023.

What treatments did the participants take?

The participants in this study took alprazolam by **inhaling** by mouth as a mist through a device or by **swallowing** it as a tablet. Doses of alprazolam were measured in milligrams (mg).

The participants, study doctors, study staff, and UCB staff knew what treatment the participants were taking.

The participants took inhaled alprazolam and alprazolam as a tablet, but in a different order. This helps researchers see how each treatment gets into the blood of each participant. Between each treatment, the participants did not take any study treatment for 8 to 12 days. This is called a “washout period”. It was done to make sure the study treatment could leave their bodies before they took the next treatment.



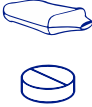

This study had 2 groups:

- **Group 1:** The participants **first took inhaled alprazolam** by mouth as a mist and then swallowed alprazolam as a tablet.
- **Group 2:** The participants **first swallowed alprazolam as a tablet** and then inhaled alprazolam by mouth as a mist.

The researchers used a computer program to randomly choose the order that each participant took the treatments. This helped make sure the treatments were chosen fairly and comparing the results for the treatments was as accurate as possible.

Clinical Study Results

The chart below shows the treatments the researchers planned to study.

	Group 1	Group 2
	11 participants	10 participants
	2 mg of alprazolam	
	Inhaled as a mist by mouth through a device and swallowed as a tablet	
	1 dose inhaled by mouth, then 1 dose swallowed as a tablet	1 dose swallowed as a tablet, then 1 dose inhaled by mouth

What happened during this study?

This section shows how the study was planned to be done.

Before joining the study, the participants visited their clinic 1 time. All the participants first learned about the study and then decided to join. This is called “informed consent”. Then, the study doctors and study staff asked the participants about their medical history and checked their health to make sure they could join the study. This part lasted up to 4 weeks. At this visit, the study doctors also:



Did physical exams and asked about the participants’ medications



Took blood and urine samples



Checked the participants’ heart health using an electrocardiogram (ECG)



Measured the level of oxygen in the participants’ blood



Asked the participants to answer questions that assessed the risks of thoughts of suicide



Gave a COVID-19 test

During the study, the participants visited their clinic 2 times. This part of the study was called the **treatment period**. On both visits, the participants stayed at the clinic for 5 days. They got their dose of study treatment on the second day of each stay. After the first 5-day visit, the participants left the clinic for 3 to 7 days for a “washout period”. During this time, the participants did not take any study treatment. Then the participants returned to the clinic and repeated what happened at the first visit, except they took their second form of study treatment.

During both of the participants’ stays at the study clinic, the study doctors kept track of any medical problems reported by the participants or observed by the doctors or study staff. The study doctors also repeated a lot of the tests and procedures that were done before the participants joined the study.

After the final treatment period, the participants visited their clinic 1 more time. This part of the study lasted up to 5 days. During this visit, the study doctors also repeated a lot of the tests and procedures that were done before the participants joined the study and during the study.

What were the results of this study?

This is a summary of the main results from this study. These are the results from all the participants combined. The individual results of each participant might be different and are not in this summary.

Deciding which treatments work best usually takes results from several studies. Other studies may provide new information or different results. Always talk to a doctor before making any treatment decisions.

Was the amount of alprazolam that got into the participants' blood different when it was inhaled by mouth as a mist compared to when it was swallowed as a tablet?

Yes. Overall, the researchers found that the amount of alprazolam that got into the participants' blood was different when alprazolam was inhaled by mouth as a mist compared to when it was swallowed as a tablet.

To answer this question, the study doctors took blood samples from the participants throughout the study. In these samples, the study doctors measured:

- The average **total** amount of alprazolam in the participants' blood
- The average **highest** amount of alprazolam in the participants' blood

Then, the researchers compared the results after the participants took inhaled alprazolam by mouth with the results after they swallowed it as a tablet. The researchers found that:

- The average **total** amount of alprazolam in the participants' blood was around **15% lower** when it was **inhaled** by mouth compared to when it was **swallowed** as a tablet
- The average **highest** amount of alprazolam in the participants' blood was around **43% higher** when it was **inhaled** by mouth compared to when it was **swallowed** as a tablet

What medical problems did the study doctors report as possibly related to the study treatments?

This section is a summary of the medical problems that the participants had during the study that the doctors reported as **possibly related** to the study treatments. These medical problems are called “**adverse reactions**”.

This summary also includes information about serious adverse reactions. An adverse reaction is considered “serious” when it is life-threatening, causes lasting problems, or requires hospital care.

Other studies may or may not show that these medical problems were related to the study treatments. The results from several studies are often needed to decide if a treatment causes an adverse reaction. Always talk to a doctor before making any treatment decisions.

Some participants had more than 1 adverse reaction.

There was 1 participant in Group 1 who took inhaled alprazolam by mouth but left the study without swallowing it as a tablet. A new participant joined Group 1 to replace the participant who left the study, and that participant took both treatments.

Did any adverse reactions happen during this study?

	Alprazolam inhaled by mouth (out of 21 participants)	Alprazolam swallowed as a tablet (out of 20 participants)
How many participants had serious adverse reactions?	none	none
How many participants had adverse reactions?	23.8% (5 participants)	none
How many participants left the study due to adverse reactions?	4.8% (1 participant)	none

What serious adverse reactions did the participants have?

None of the participants had serious adverse reactions in this study.

What adverse reactions did the participants have?

The most common adverse reaction was decrease in blood oxygen levels.

The table below shows all the adverse reactions that happened in this study.

Adverse reaction	Alprazolam inhaled by mouth (out of 21 participants)	Alprazolam swallowed as a tablet (out of 20 participants)
Decrease in blood oxygen levels	19.0% (4 participants)	none
Low energy or tiredness (Lethargy)	14.3% (3 participants)	none
Anxiety	4.8% (1 participant)	none
Feeling sleepy (Somnolence)	4.8% (1 participant)	none
Low blood pressure (Hypotension)	4.8% (1 participant)	none

What did the researchers learn from this study?

The results of this study have helped researchers learn more about how much alprazolam gets into the bodies of healthy participants when inhaled by mouth as a mist and when swallowed as a tablet.

Deciding which treatments work best for patients almost always takes results from several studies. This summary shows only the main results from this one study. Other studies may provide new information or different results.

The purpose of this summary is only to share information. If you need medical advice about your own health or situation, please contact your doctor.

At the time this document was approved, further clinical studies with alprazolam were planned.

Where can I learn more about this study?

You can find more information about this study at the website listed below:

- www.clinicaltrials.gov/ct2/show/study/NCT05626439

If you have questions about this study, UCB contact information is available at www.ucb.com/UCBcares.

Study Information

Protocol Number: UP0104

Study Sponsor: UCB Biopharma SRL sponsored this study. It is referred to as UCB in this summary.

Full Study Title: An Open-Label, Randomized, Single-Dose, 2-Way Crossover Study to Evaluate The Relative Bioavailability of Staccato Alprazolam Compared to Oral Alprazolam in Healthy Study Participants

National Clinical Study Number: NCT05626439

Thank you

Participants in clinical studies 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.



This summary was last updated on 21 March 2024.
The final clinical study report is dated 04 October 2023.