

Results on the effects and safety of AFQ056 for people with Cocaine Use Disorder



Thank you!

Thank you to the participants who took part in the clinical trial for the trial drug **AFQ056**, also known as mavoglurant. All of the participants helped the researchers learn more about how AFQ056 works and how safe it is to take.

Novartis sponsored this trial and believes it is important to share what was learned from the results of this trial with the participants and the public. An independent organization prepared this summary of the trial results.

We hope this helps the participants understand their important role in medical research.



If you participated in the trial and have **questions** about the results, please speak with the trial doctors or staff at your trial site.

Trial information

Trial number: CAFQ056X2201

Drug studied: AFQ056 (mavoglurant)

Sponsor: Novartis

This trial at a glance

What was the purpose of this trial?

[Read more on page 3](#)



This trial's purpose was to learn if the participants used cocaine on fewer days while taking the trial drug AFQ056. All the participants in this trial had Cocaine Use Disorder, also called CUD. A person with CUD continues to use cocaine, despite the problems it causes to their health, with family and friends, or at work.

The main questions this trial was designed to answer were:

- Did the participants who took AFQ056 report using cocaine on fewer days during trial treatment?
- What medical problems did the participants have during this trial? Keeping track of the medical problems helped to learn about the safety of AFQ056.

Who was in this trial?

[Read more on pages 3-4](#)



- 68 men and women began this trial
- The participants were 18 to 57 years old and had CUD

What trial treatments did the participants take?

[Read more on page 4](#)



Each participant was assigned one of these treatments:

- **AFQ056**
- **Placebo** – looks like the trial drug but has no trial drug in it. Using a placebo helps researchers better understand the actual effects of a trial drug.

The participants took their assigned treatment as pills.

What were the main results of this trial?

[Read more on pages 5-8](#)



- Participants who took AFQ056 reported using cocaine on fewer days during treatment compared to those who took the placebo.
- The number of participants who had medical problems was similar between those who took AFQ056 and the placebo. The most common medical problem was headache.

[Read about other results of this trial on page 9](#)



You can find **more information** about this trial by going to the websites listed on [page 10](#).

What was the purpose of this clinical trial?

The purpose of this trial was to help researchers find better ways to treat **Cocaine Use Disorder**, also called **CUD**. CUD is a disorder in which a person continues to use cocaine, despite the problems it causes to their health, with family and friends, or at work. Long-term cocaine use can alter how the brain works and can cause serious health problems such as addiction, heart disease, and stroke.

This trial was designed to learn if people with CUD used cocaine on fewer days while taking AFQ056. **AFQ056** is a trial drug that researchers think could help people with CUD use cocaine less often. AFQ056 blocks a certain protein in the brain, which research has shown is related to people's craving to use drugs such as cocaine.

Before a drug can be approved for doctors to prescribe, researchers do many trials to find out how safe it is and how well it works.

The main questions this trial was designed to answer were:

- Did the participants who took AFQ056 report using cocaine on fewer days during trial treatment?
- What medical problems did the participants have during this trial? Keeping track of the medical problems helped to learn about the safety of AFQ056.

How long was this trial?

This trial began in December 2017 and ended in December 2019. Most participants took part in this trial for about 20 weeks.

Who was in this trial?

68 participants took a trial treatment – 56 men and 12 women. The participants were 18 to 57 years old. Their average age was 35.

Every participant in this trial had CUD. They also:

- Usually snorted their cocaine
- Were seeking treatment to help them use cocaine less often
- Didn't use cocaine for at least 3 days before treatment
- Didn't have a moderate-to-severe substance use disorder for alcohol, cannabis, opioids, or stimulants other than cocaine
- Were in otherwise good overall mental and physical health

14 participants did not complete this trial.

This trial took place in Argentina, Spain, and Switzerland.



Visit novctrd.com for more information about:

- Who could and could not be in this trial
- The participants in this trial, such as their age, gender, and race

Use trial number **CAFQ056X2201** to find the scientific summary.

What trial treatments did the participants take?



A computer program was used to randomly assign each participant the treatment they took:

- **AFQ056** – 50 to 200 milligrams (mg)
- **Placebo** – looks like the trial drug but has no trial drug in it. Using a placebo helps researchers better understand the actual effects of a trial drug.

Using a computer program to assign the treatments helped make sure the team compared the results as fairly as possible.



The participants took their assigned treatment as pills 2 times a day for 14 weeks.

The participants who took AFQ056 received an increasing dose over 3 weeks. This allowed their bodies to adjust to AFQ056, so they did not have as many unwanted effects. The doses were:

- 50 milligrams (mg) during the 1st week of treatment
- 100 mg during the 2nd week
- 200 mg starting on the 3rd week and continued until their last dose

The participants and trial staff did not know what treatment each participant took during the trial. Some trials are done this way because knowing what treatment participants take can influence the results. Not knowing what treatment participants take helps make sure the results are looked at fairly.

What were the main results of this trial?



This is a summary of the overall results of this trial. Individual results from each participant may be different and are not included in this summary.

Researchers need many trials to learn if a drug or other trial treatment is safe and works well. Other trials may provide new information or different results.

Always talk to a doctor before making any changes to your health care.

Did the participants who took AFQ056 report using cocaine on fewer days during trial treatment?

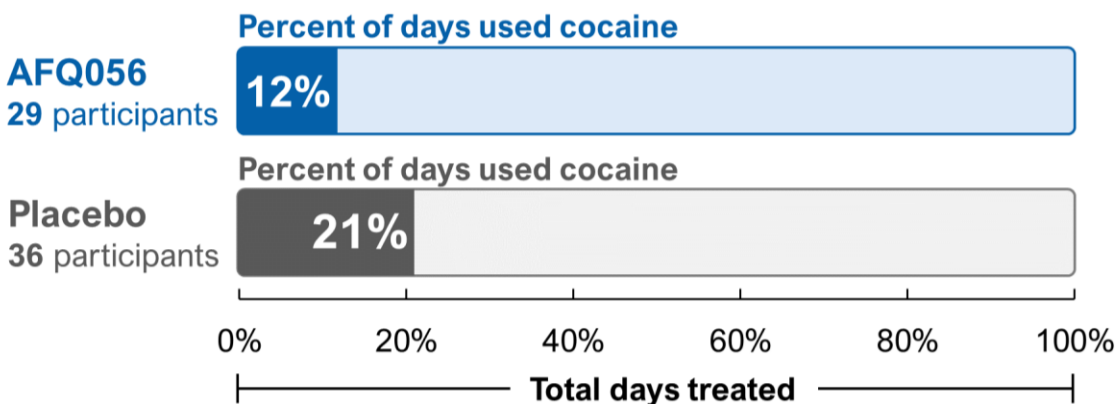


The participants who took AFQ056 reported using cocaine on fewer days during treatment compared to those who took the placebo.

To find this out, the clinical trial team counted how many days each participant reported using cocaine and the number of days they took their assigned treatment. Then, the team compared the number of days for participants who took AFQ056 to those who took the placebo.

The team found that the participants who took AFQ056 reported using cocaine on about 12% of their total days of treatment. This is about 12 days out of 98 days of treatment. The participants who took the placebo reported using cocaine on about 21% of their total days of treatment. This is about 20 days out of 98 days of treatment.

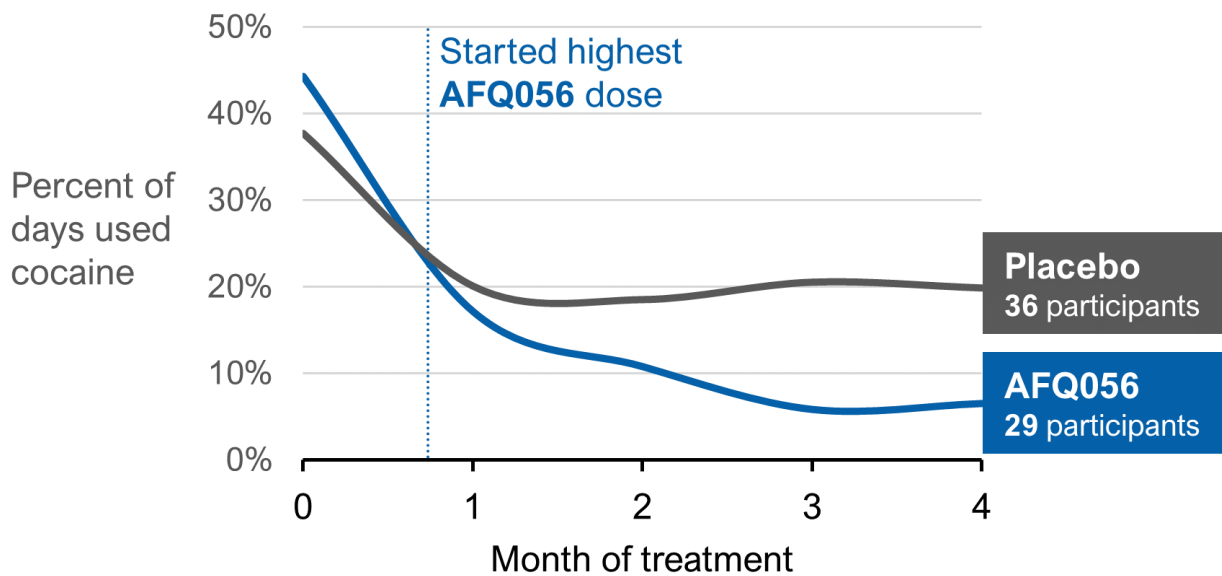
Average percent of days the participants used cocaine during treatment



Note: This graph doesn't include results from certain participants, such as those who took their treatment for less than 2 weeks.

The graph below shows how the participants' cocaine use changed over time. The participants who took AFQ056 started receiving the highest dose during their 3rd week of treatment. After they started the highest dose, the participants who took AFQ056 used cocaine for fewer days each month compared to those who took the placebo.

Average percent of days participants used cocaine during each month of treatment



Note: This graph doesn't include results from certain participants, such as those who took their treatment for less than 2 weeks.

What medical problems did the participants have during this trial?

Medical problems that happen during trials are called “adverse events”. Trial doctors looked for any adverse events when they checked the participants’ blood and urine samples and during the visits to the trial site. The participants also reported adverse events. This section includes the adverse events that happened during and after trial treatment.

Many trials are needed to know if a drug or treatment causes an adverse event. Trial doctors keep track of all adverse events that happen in trials, even if they think the adverse events might not be related to the trial treatments.

What is an adverse event?

- An **adverse event** is any unwanted sign or symptom that participants have during a trial
- It is considered “**serious**” when it is life-threatening, causes lasting problems, the participant needs hospital care, or results in death
- Adverse events **may or may not be caused** by trial treatments



The number of participants who had adverse events was similar between those who took AFQ056 and the placebo. The most common adverse event was headache.

Participants who had adverse events

Participants who had:	AFQ056 31 participants	Placebo 37 participants
Serious adverse events	0% 0 of 31	3% 1 of 37
Non-serious adverse events	84% 26 of 31	81% 30 of 37
Left this trial due to adverse events	6% 2 of 31	3% 1 of 37

What serious adverse events did the participants have?

No participants who took AFQ056 had serious adverse events.

One participant who took the placebo had a serious adverse event which was **feeling overly nervous or anxious** (agitation).

No other serious adverse events were reported during this trial, including deaths.

What non-serious adverse events did the participants have?

Most of the participants had adverse events that were not serious. The table below shows the adverse events that happened to **7 or more participants**. Other adverse events were reported by fewer participants.

Non-serious adverse events

	AFQ056 31 participants	Placebo 37 participants
Headache	19% 6 of 31	27% 10 of 37
Dizziness	23% 7 of 31	11% 4 of 37
Upper belly pain Abdominal pain upper	10% 3 of 31	19% 7 of 37
Common cold Nasopharyngitis	6% 2 of 31	22% 8 of 37
Back pain	13% 4 of 31	14% 5 of 37
Feeling sick to the stomach Nausea	19% 6 of 31	8% 3 of 37
Anxiety	10% 3 of 31	11% 4 of 37
Diarrhea	6% 2 of 31	14% 5 of 37
Trouble falling asleep Insomnia	16% 5 of 31	5% 2 of 37



Visit novctrd.com for more information about the adverse events the participants in this trial had. Use trial number **CAFQ056X2201** to find the scientific summary.

What other results were learned?

Did the participants who took AFQ056 have lower levels of a cocaine metabolite in their urine?

After a person uses a drug, such as cocaine, their body breaks it down into a substance called a metabolite. One way the body removes certain metabolites is through urine. As another way to track participants' cocaine use, the clinical trial team measured the level of a cocaine metabolite in each participant's urine. Lower levels of the metabolite mean a person used less cocaine.

The participants who took AFQ056 had lower levels of the cocaine metabolite in their urine compared to those who took the placebo.

Did AFQ056 change the participants' reported alcohol use?

The team asked each participant to keep track of their alcohol use. They counted the total number of days participants reported drinking alcohol during treatment. They also looked at how many weeks participants did not drink any alcohol.

The participants who took AFQ056 reported drinking alcohol on fewer days during treatment compared to those who took the placebo. They also had more weeks without drinking any alcohol.

What was learned from this trial?

This was the first trial to learn about how well AFQ056 works and how safe it is for people with CUD. The clinical trial team found that the participants who took AFQ056 reported using cocaine on fewer days during treatment compared to those who took the placebo. They also found it was safe for the participants in this trial.

This was one of many trials a drug must go through before it can be approved for doctors to prescribe. This type of trial learns about the safety of a trial drug and how well it works in a small number of participants.



The results presented here are for one trial. One trial cannot give a complete picture of the benefits and risks of a trial drug. The results of many trials are needed to find out which treatments can be used for people with CUD. This summary shows only the main results from this trial. Other trials may provide new information or different results.

Where can I learn more about this and future clinical trials?



This is a summary of the results for one trial.

You can find detailed results and more information about this clinical trial on the Novartis Clinical Trial Results website:

1. Visit novctrd.com
2. Click on either “Clinical Trial Results” or “Trial Summaries for Patients” at the top right of the page
3. Read and scroll down, then click “I accept” to agree to use the information and the website
4. Select “Study number” from the drop-down menu
5. Type “**CAFQ056X2201**” in the search box and click search

If you would like to view the website in a language other than English, you can click the “Google Translate” button on the top right of the page.



If you were in this trial and have questions about the results, please speak with the doctor or staff at your trial site.

This trial was registered on the following websites:

- ClinicalTrials.gov – <https://clinicaltrials.gov/>
To find this trial, type **CAFQ056X2201** in the **Other terms** search box
- European Union Clinical Trials Register – <https://www.clinicaltrialsregister.eu/ctr-search>
To find this trial, type **CAFQ056X2201** in the search box

Full trial title:

A randomized, subject- and Investigator-blinded, placebo-controlled, parallel-group study to investigate whether AFQ056 reduces cocaine use in patients diagnosed with Cocaine Use Disorder (CUD)

If more trials are planned, they will appear on the public websites listed above. When there, search for **AFQ056** or **mavoglurant**.

Thank you!

Novartis would like to thank all of the people who participated in this clinical trial. The participants made this clinical trial possible and helped researchers answer important health questions and learn about a possible medical treatment. Many volunteers and many clinical trials are needed to advance medical science.



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