

The effects of QAW039 for people with COPD



Thank you!

Thank you to the participants who took part in the clinical trial for the trial drug **QAW039**, also called fevipiprant. All of the participants helped the researchers learn more about the safety of QAW039. If you participated in the trial and have questions about the results, please speak with the trial doctors or staff at your trial site.

What was the purpose of this trial?

The purpose of this trial was to learn if QAW039 could reduce the level of eosinophils in the lungs for people with COPD, which stands for chronic obstructive pulmonary disease.



Eosinophils are a type of cell that usually helps the body fight infections. Researchers think that high levels of eosinophils in the lungs might worsen the symptoms of certain lung conditions, like COPD.



QAW039 is a trial drug designed to block certain immune system cells, including eosinophils, from moving to the lungs.

The main questions this trial was designed to answer:

- Did QAW039 reduce the level of eosinophils in the participants' lungs?
- What medical problems did the participants have during this trial?

Keeping track of the medical problems helped to learn about the safety of QAW039.



Main message: This clinical trial ended early. Because of this, there were too few participants for the clinical trial team to learn about the effects of QAW039 for people with COPD. The team found no safety concerns for QAW039.

How long was this trial?

The trial began in May 2019 and ended in January 2020. The trial was planned to last about 19 weeks for each participant.



The sponsor ended this trial early because other trials with QAW039 showed that it didn't work to treat people with another lung condition and high levels of eosinophils. Because of these results, the sponsor concluded that QAW039 was unlikely to help people with COPD who have high levels of eosinophils. The decision to end the trial was not related to safety. The sponsor is no longer studying QAW039 as a possible treatment for COPD.

Who was in this trial?



This trial planned for about 50 participants. Because the trial ended early, only 9 participants were in this trial – 7 men and 2 women. 3 participants did not complete this trial. The participants were 51 to 75 years old. Their average age was 65.

Every participant in this trial:

- Had moderate to severe COPD and high levels of eosinophils in their lungs
- Was taking commonly prescribed medicines for COPD
- Had smoked cigarettes daily for at least 10 years - they could be a current smoker
- Did not have any other lung-related disease, such as asthma



This trial took place in Germany and the United Kingdom.

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 **CQAW039E12201** to find the scientific summary.

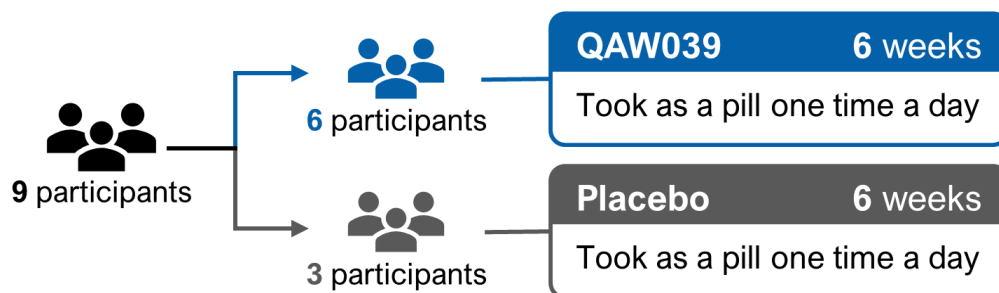
What trial treatments did the participants take?



A computer program was used to randomly assign each participant to one of the following:

- **QAW039** – 450 milligrams (mg) as a pill
- **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 graphic below shows the number of participants who received each treatment.



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 took can influence the results. Not knowing what treatment participants took helps make sure the results are looked at fairly. Each participant continued to take their regular medicines for COPD.

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 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 QAW039 reduce the level of eosinophils in the participants' lungs?



Because the trial ended early, there were too few participants for the clinical trial team to conclude if QAW039 could reduce the level of eosinophils in the participants' lungs.

The trial staff measured the level of eosinophils in the participants' lungs by counting eosinophils found in **sputum**, which is mucus or thick fluid coughed up from the lungs. They measured these levels before and after 6 weeks of treatment.



They compared
eosinophil levels:

from



Those who
took **QAW039**

with



Those who
took the **placebo**

The clinical trial team compared these measures to find out if the participants who took QAW039 had lower levels of eosinophils in their lungs after 6 weeks of treatment.

Because the trial ended early, the clinical trial team could not compare the results of the participants who took QAW039 to those who took the placebo.

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 during the visits to the trial site. The participants also reported adverse events.

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 are not related to the trial treatments.

An adverse event is:

- Any **unwanted sign or symptom** that the participants have during a trial
- 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 treatments in the trial.



No serious adverse events were reported, including deaths. 6 of the 9 participants reported other adverse events.

The most common adverse event was a broken foot bone (foot fracture). This happened to 1 participant in the QAW039 group and 1 participant in the placebo group.

What was learned from this trial?

This was the first trial to learn about the effects and safety of QAW039 in a small number of participants with COPD. The clinical trial team found no safety concerns for QAW039.

The results from other larger trials did not support further development of QAW039. QAW039 is no longer being studied as a potential treatment for people who have lung conditions and high levels of eosinophils.

Where can I learn more about this trial?

For more information about this trial, search for **CQAW039E12201** at any of these websites:

- novctrd.com Novartis clinical trial results
- clinicaltrials.gov ClinicalTrials.gov
- clinicaltrialsregister.eu/ctr-search European Union Clinical Trials Register



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