

Read about this clinical trial's results



Hello!

Thank you for being in this clinical trial!

You helped doctors learn about a trial medicine called **QGE031**. The trial medicine is for people with **food allergy**. We hope you feel proud of your role!



What is a clinical trial and why did this trial happen?

A **clinical trial** is research to learn about a trial medicine. In this trial, doctors wanted to answer the following question about **QGE031** in people with **food allergy**:

- **What medical problems happened to people during this trial?**

What is food allergy?

In people with **food allergies** like **peanut allergy**, the body thinks some foods are harmful, even when they're not. The immune system (the body's natural defense system) then makes special proteins called antibodies to try to protect the body. But the action of these antibodies causes an allergic reaction.



After eating peanuts, people with a **peanut allergy** can get skin rashes, a sore throat, stomach pain, vomiting, or have trouble breathing. Sometimes, they can get very sick.



What is QGE031?



QGE031 is a **trial medicine** that binds to the antibody produced in response to peanuts and may stop it from causing allergy. People in this trial were given **QGE031** as an injection under the skin once a month.



A trial medicine is a medicine that doctors are studying to learn if it works.



Doctors studied two doses of **QGE031** in this trial:

- **120 milligrams**: called '**low dose**' in this summary
- **240 milligrams**: called '**high dose**' in this summary

Who was in this trial?



163

people were in this trial. Everyone had **food allergy** and had completed treatment in a previous **QGE031** trial for **peanut allergy**.



90
Males



12

to

47

years old



73
Females

Where did this trial take place?

The map below shows how many people took part in each country.



What happened during this trial?



People continued receiving the treatment they received in the previous trial, in one of these groups:

- **Low dose of QGE031**
- **High dose of QGE031**

People in the **low dose** group also received **placebo**. This was used to make sure that everyone got the same number of injections. This is important in clinical trials so that no one can guess which treatment they are getting, which helps keep the results fair and reliable.



What's a placebo?



A **placebo** has no medicine in it, but looks like the trial medicine.

**Low dose
QGE031**



**High dose
QGE031**



81 people received the **low dose of QGE031** along with **placebo**



82 people received the **high dose of QGE031**

People got QGE031 for about 1 year and 3 months.

The people taking part and the doctors did not know if they were receiving the **low** or **high** dose of **QGE031**. This helps to make sure that the results are looked at with fairness across all treatments.



- During the trial, people were given peanut protein to see how much they could eat without having a reaction.
- Some people who could eat the maximum amount of peanut protein at the end of the previous trial were able to stop the medicine at the beginning of this trial. If those people's allergy symptoms returned, they could restart the medicine.



The researchers stopped the trial earlier than planned, but not because of any medical problems.

What was learned from this trial?

What medical problems happened to people during this trial?



Doctors checked people and wrote down all the medical problems they had during the trial, even if they were not caused by **QGE031**.



Answer

Most people had medical problems during this trial. 5 people had serious medical problems.

The serious medical problems were:



Damage to the heart muscle



Diabetes



Difficulty breathing



Feeling sick



Inflamed colon



Itching due to allergy



Lip swelling



Sudden, severe allergic reaction



Swollen tongue



Swollen face



Throat irritation



Throat swelling

What was learned from this trial?

Other common medical problems were:



Common cold



Infection of the nose and throat



Cough



Inflamed stomach and intestine



COVID-19 Infection



Injection site swelling due to fluid build-up



Flu



Redness at the injection site



Hardness or thickening at the injection site



Swelling at the injection site



Headache

Thank you!

Trials like this cannot happen without you and others who join.



Doctors need the results from many trials to find new, possible medicines. We learned many things about **QGE031** from this trial.



If you would like to **learn more**, ask a parent or another adult, or read the main summary for this trial at: www.novctrd.com

Search with the trial number
CQGE031G12303B



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