Clinical Study Results

AstraZeneca

Research Sponsor: AstraZeneca AB

Drug Studied: Omega-3 carboxylic acids

Study Title: A study to learn how omega-3 carboxylic acids act in the blood of healthy Chinese participants

Thank you!

Thank you to the participants who took part in the clinical trial for the study drug omega-3 carboxylic acids.

AstraZeneca AB sponsored this study and thinks it is important to share the results. An independent non-profit organization called CISCRP helped prepare this summary of the study results for you.

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

What is happening with the study now?

The study started and ended in June 2018. The sponsor reviewed the data collected when the study ended and created a report of the results. This is a summary of that report.

There were 16 Chinese participants who joined the study in China, but only 14 participants took the study drug. The doctors decided that 2 of the participants should not take the study drug.

Why was the research needed?

Researchers are looking for a better way to treat people with high levels of triglycerides in their blood. Before a drug can be approved for patients to take, researchers do clinical studies to find out how safe it is and how it works.

Triglycerides are a type of fat that is found in the blood and is also stored in the liver and in fat cells. High levels of triglycerides can be a result of a high-fat diet. If someone has a high level of triglycerides in their blood, their chance of getting heart disease can increase.

The study drug, “omega-3 carboxylic acids”, contains certain fats that comes from fish oil that are known to lower triglyceride levels in the blood. A capsule form of omega-3 carboxylic acids has been tested in the United States for the treatment of high levels of triglycerides. In this study, the researchers wanted to learn how omega-3 carboxylic acids act in the blood of healthy Chinese participants.

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

- How did omega-3 carboxylic acids act in the blood?
- What medical problems did the participants have during the study?

The answers to these questions are important to know before other studies can be done that help find out if omega-3 carboxylic acids improve the health of people with high levels of triglycerides.

The researchers asked for the help of healthy Chinese men and women living in China. Everyone in the study was 23 to 41 years old when they joined.

What kind of study was this?

This was an "open-label" study. This means the researchers and the participant knew what the participant was taking. All of the participants took omega-3 carboxylic acids by mouth. Each dose was 4 grams.

First, the participants took 1 dose of omega-3 carboxylic acids. They waited 72 hours before taking the next dose, so that all of the study drug could leave their body. Then, they took 1 dose of omega-3 carboxylic acids every day for 14 days.

What happened during the study?

Before treatment, the doctors checked the participants' health to make sure they could join the study. They did a test called an electrocardiogram to check the participants' heart health. An electrocardiogram is also called an ECG. Participants were admitted to the study site 2 days before the first dose of the study drug was taken.

During treatment, the participants stayed at the study site for 19 days and took omega-3 carboxylic acids on Day 1 and Days 4 to 17. Then, the participants stayed at the study site for 1 more day but did not take the study drug.

Throughout the study, the doctors:

- checked the participants' overall health
- asked the participants how they were feeling
- took blood and urine samples on certain days

What were the results of the study?

This is a summary of the main results from this study. The results each participant had might be different and are not in this summary.

Researchers look at the results of many studies to decide which treatments work best and are safest. Other studies may provide new information or different results. Always talk to a doctor before making any treatment change.

The websites listed at the end of this summary may have a full report of the study results.

How did omega-3 carboxylic acids act in the blood?

Omega-3 carboxylic acids is a mixture of several kinds of carboxylic acids. The researchers studied 2 of the carboxylic acids that make up the largest parts of the mixture. One is eicosapentaenoic acid, also called EPA. The other is docosahexaenoic acid, also called DHA.

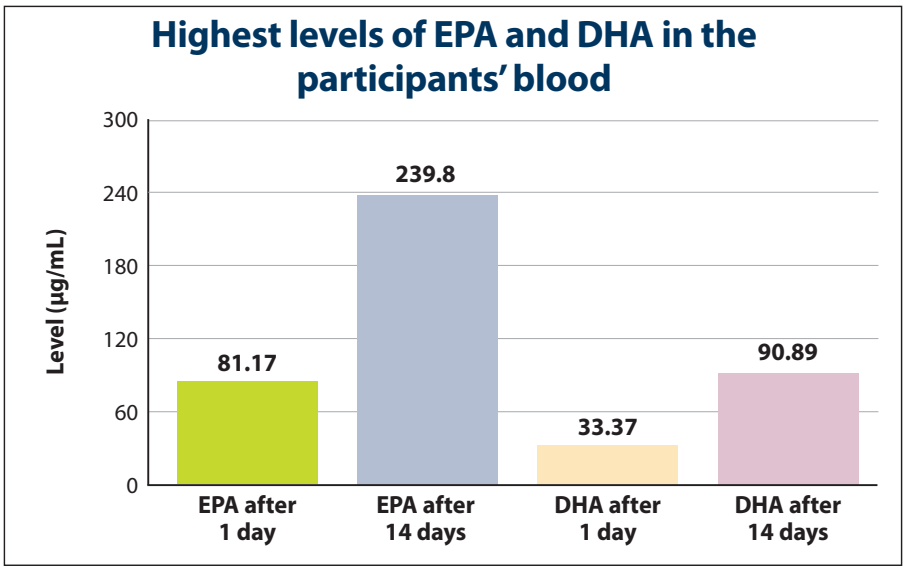
The researchers measured the levels of EPA and DHA in the blood of participants before and at different times after they took omega-3 carboxylic acids. This helped the researchers find:

- the highest levels of EPA and DHA in the blood
- the total amounts of EPA and DHA in the blood over 24 hours
- how long it took for EPA and DHA to reach their highest levels in the blood

Highest levels of EPA and DHA in the blood

For both EPA and DHA, the highest levels in the participants' blood after they took 1 dose of omega-3 carboxylic acids every day for 14 days were about 3 times the highest levels after they took 1 dose of omega-3 carboxylic acids for 1 day.

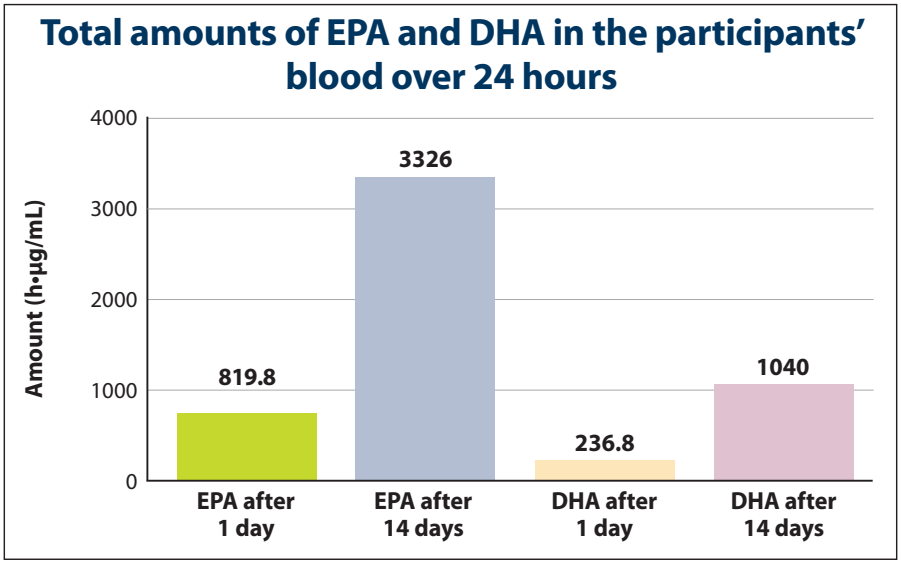
The chart below shows the highest levels of EPA and DHA in the blood after taking omega-3 carboxylic acids for 1 day and for 14 days. These levels are measured in micrograms per milliliter of blood, also called µg/mL.



Total amounts of EPA and DHA in the blood over 24 hours

For both EPA and DHA, the total amounts in the participants' blood over 24 hours after they took omega-3 carboxylic acids for 14 days were about 4 times the total amounts after they took a single dose of omega-3 carboxylic acids for 1 day.

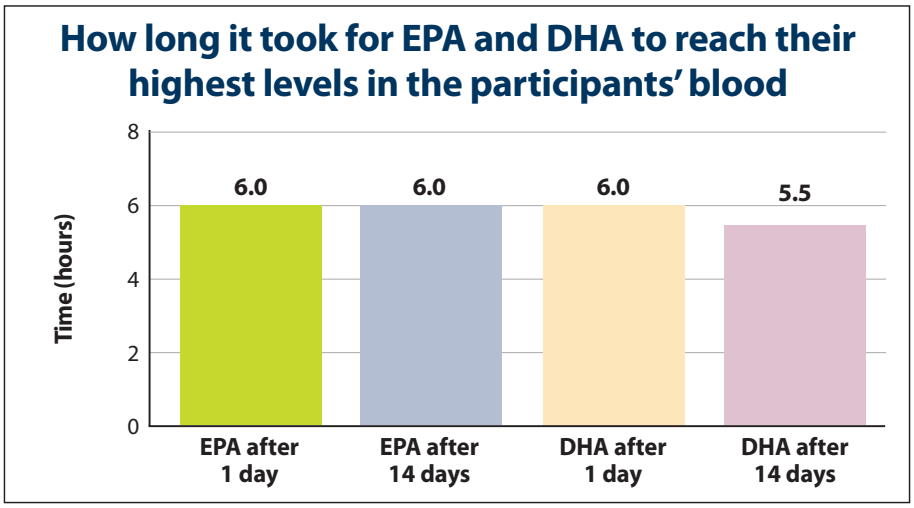
The chart below shows the total amounts of EPA and DHA in the blood over 24 hours after they took omega-3 carboxylic acids for 1 day and for 14 days. These amounts are measured in hours multiplied by micrograms per milliliter of blood, also called h•µg/mL.



How long it took for EPA and DHA to reach their highest levels in the blood

It took about the same amount of time for EPA and DHA to reach their highest levels in the participants' blood after they took omega-3 carboxylic acids for 1 day and for 14 days.

The chart below shows how long it took for EPA and DHA to reach their highest levels in the blood after participants took omega-3 carboxylic acids for 1 day and for 14 days. This is measured in hours.



What medical problems did the participants have during the study?

This section is a summary of the medical problems the participants had during the study that the study doctors thought might be related to the study drug. These medical problems are called “adverse reactions”. An adverse reaction is considered “serious” when it is life-threatening, causes lasting problems, or requires hospital care.

These adverse reactions may or may not be caused by the study drug. A lot of research is needed to know whether a drug causes an adverse reaction.

The websites listed at the end of this summary may have other information about adverse reactions or other medical problems that happened during this study.

How many participants had serious adverse reactions?

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

How many participants had adverse reactions?

There were 42.9% of participants who had adverse reactions during the study. This was 6 out of 14 participants. The only type of adverse reaction in the study was diarrhea.

None of the participants stopped taking omega-3 carboxylic acids during the study because of adverse reactions.

How has this study helped participants and researchers?

The results from this study helped the researchers learn how omega-3 carboxylic acids act in healthy Chinese participants.

Researchers look at the results of many studies to decide which treatments work best and are safest. This summary shows only the main results from this one study. Other studies may provide new information or different results.

Further clinical studies with omega-3 carboxylic acids are ongoing.

Where can I learn more about this study?

You can find more information about this study on the websites listed below. If a full report of the study results is available, it can also be found here.

- www.clinicaltrials.gov. Once you are on the website, type **"NCT03574142"** into the search box and click **"Search"**.
- www.AstraZenecaClinicalTrials.com. Once you are on the website, type **"D5881C00001"** into the search box and click **"Find a Study"**.

Full Trial Title: A Phase I, Open-label Study to Evaluate the Pharmacokinetics of Single and Multiple Doses of Epanova® in Chinese Healthy Subjects Living in China

AstraZeneca Protocol Number: D5881C00001

AstraZeneca AB sponsored this study and has its headquarters at 151 85 Södertälje, Sweden.

The phone number for the AstraZeneca Information Center is +1-877-240-9479.

Thank you!

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 participants.