Clinical Study Results

AstraZeneca

Research sponsor: AstraZeneca AB

Drug studied: Durvalumab

Study title: A study to learn how durvalumab by itself or durvalumab together with tremelimumab affects patients with pancreatic cancer

Thank you!

Thank you for taking part in the clinical study for the drugs durvalumab and tremelimumab. These drugs are being developed to treat patients with pancreatic cancer, as well as other types of cancer. You and all of the participants are helping researchers learn how durvalumab by itself and durvalumab together with tremelimumab can be used to potentially treat pancreatic cancer and if these drugs cause medical problems.

AstraZeneca AB sponsored this study and thinks it is important to share the results of the study with you and the public. An independent, non-profit organization called CISCRP and a medical writing organization called Synchrogenix helped prepare this summary of the study results for you. We hope it helps you understand and feel proud of your important role in medical research.

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?

You and the other participants were in the study for up to 1 year. But, the entire study took almost a year and a half to finish.

The study started in November 2015 and ended in March 2017. The study included 65 participants at 21 study sites in Canada, Germany, the Netherlands, South Korea, Spain, and the United States.

The study had 2 parts: Part A and Part B. Part B did not enroll any participants because researchers did not think the results for Part A were good enough to proceed to Part B. So, the study ended after Part A was completed. The sponsor reviewed the data collected in the study and created a report of the results. This is a summary of that report.

Why was the research needed?

Researchers are looking for a treatment for patients with pancreatic cancer. Before a drug can be approved for participants to take, researchers do clinical studies to find out how it works and how safe it is.

In this study, the researchers wanted to find out if durvalumab and tremelimumab work in a small number of participants with metastatic pancreatic cancer. They also wanted to find out if participants had any medical problems during the study.

The study drugs, durvalumab and tremelimumab, are being developed to treat pancreatic cancer. Researchers wanted to learn how these drugs affect participants with metastatic pancreatic cancer when durvalumab is given alone or when the 2 drugs are given together. These drugs are both used to treat cancer, but in different ways.

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

- Did durvalumab help participants' tumors shrink or disappear when the drug was given either alone or given together with tremelimumab?
- What medical problems did participants have during the study?

To answer the questions in this study, researchers asked for the help of men and women with metastatic pancreatic cancer. The participants in this study were 37 to 81 years old.

What kind of study was this?

This was an "open-label" study. This means that the researchers and the participant knew what study drugs the participant was getting.

A computer program was used to randomly choose the treatment each participant got. This helps make sure the groups are chosen fairly. Researchers do this so that comparing the results of each treatment is as accurate as possible.

What happened during the study?

To see if you could join the study, study doctors did a physical examination by checking your height, weight, blood pressure, pulse, and temperature. Study doctors took blood and urine samples and checked your heart health using an electrocardiogram, also known as an ECG. Study doctors also asked about your medical history, how you were feeling, and what medicines you were taking.

Study doctors also did computed tomography scans, or CT scans, on participants throughout the study. These scans help doctors look at the inside of the body and study diseases, such as cancer.

Participants in this study were placed into 1 of 2 treatment groups. One treatment group got only durvalumab, and the other treatment group got durvalumab and tremelimumab.

Participants in both treatment groups visited their study site at least 20 times.

Durvalumab-only group

In this treatment group, 33 participants were assigned to get treatment with durvalumab. Of these, 32 got an injection of 1.5 grams of durvalumab once every 4 weeks for up to 1 year at their study site. One of these 33 participants left the study before the researchers could collect all of the study data.

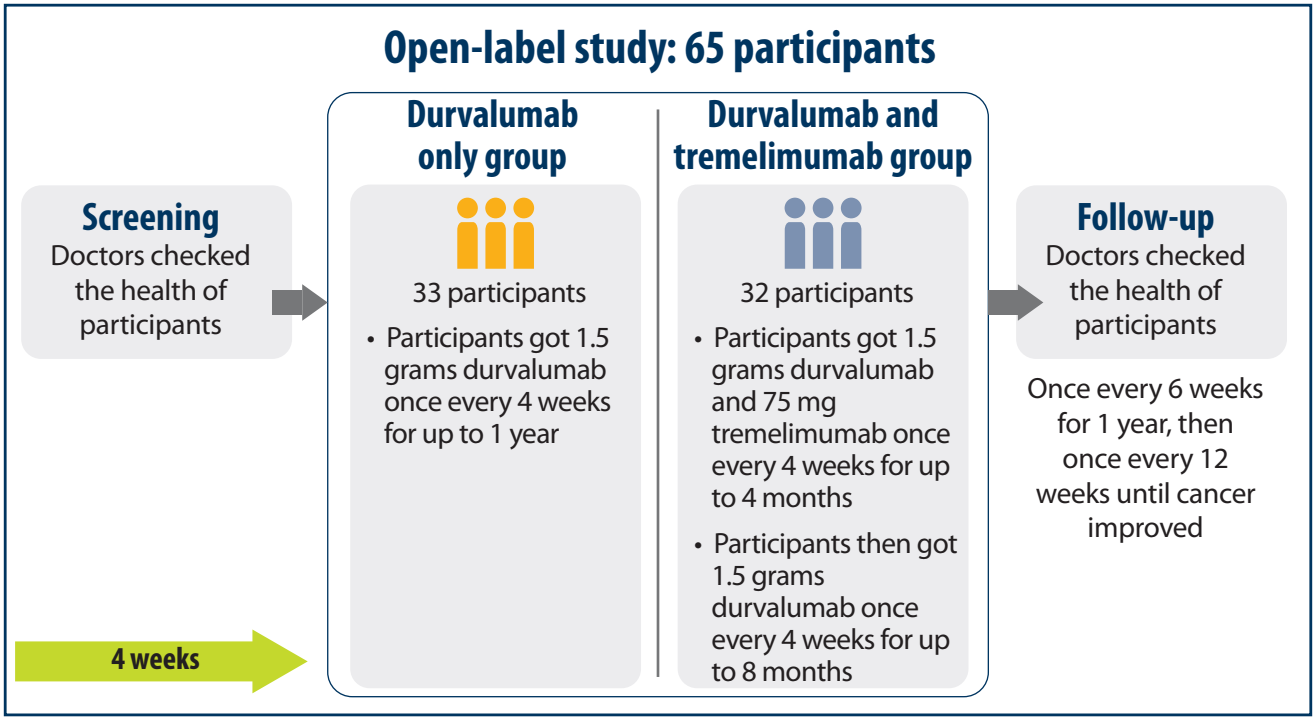
Durvalumab and tremelimumab group

In this treatment group, 32 participants got injections of 1.5 grams of durvalumab and 75 milligrams, also known as mg, of tremelimumab once every 4 weeks for up to 4 months at their study site.

Then, these participants got an injection of 1.5 grams of durvalumab once every 4 weeks for up to 8 months.

After treatment ended, the study doctors checked the health of participants in both treatment groups. All participants visited their site once every 6 weeks for 1 year and then once every 12 weeks until their tumors shrank or disappeared.

The figure below shows how the study was done.



What were the results of the study?

This is a summary of the main results from this study overall. The results each participant had might be different and are not in this summary. A full list of the questions researchers wanted to answer can be found on the websites listed at the end of this summary. If a full report of the study results is available, it can also be found on these websites.

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 changes.

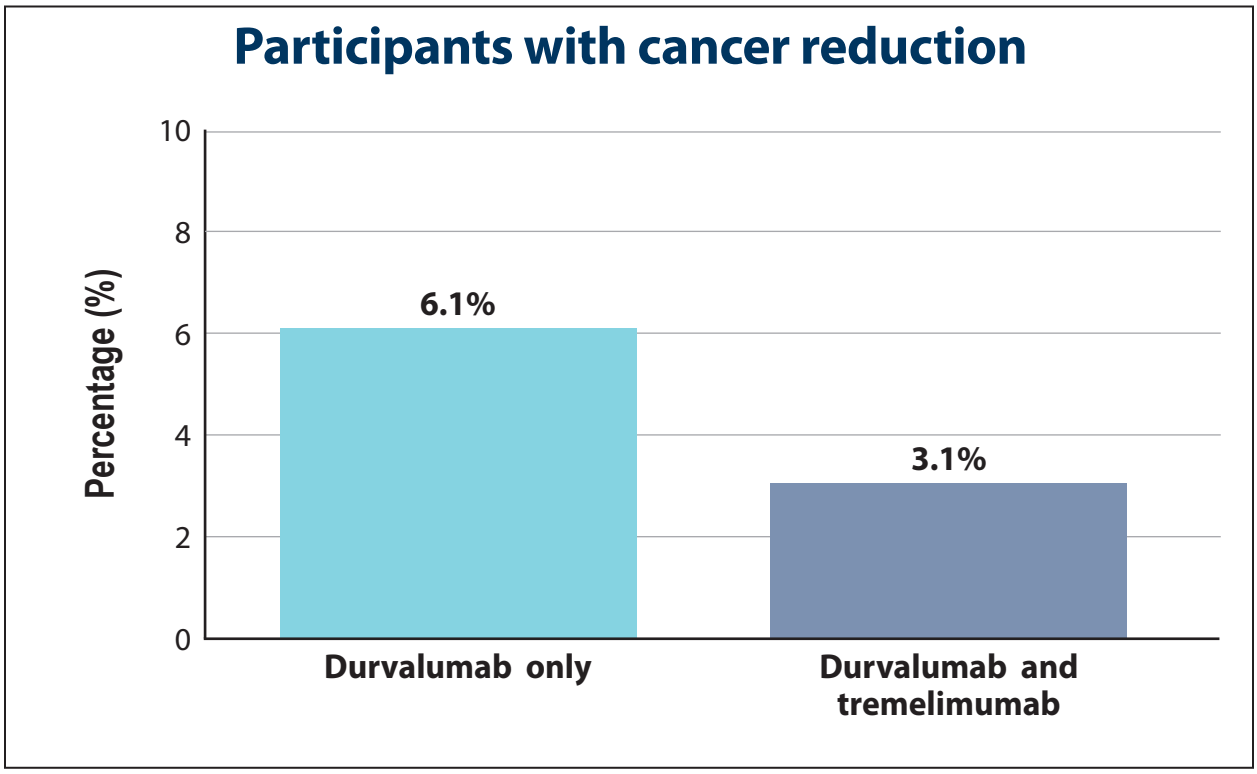
Did durvalumab help participants' tumors shrink or disappear when the drug was given either alone or given together with tremelimumab?

The researchers wanted to learn if durvalumab and tremelimumab help participants with pancreatic cancer. A small number of participants in both treatment groups had their tumors shrink, but researchers could not tell if these changes were related to the study drugs.

The researchers found that:

- 6.1% of participants had their tumors shrink or disappear in the durvalumab-only treatment group. This was 2 out of 33 participants. However, researchers could not tell if these changes were related to the durvalumab treatment.
- 3.1% of participants had their tumors shrink or disappear in the durvalumab and tremelimumab treatment group. This was 1 out of 32 participants. The researchers thought that this change was related to the treatment.

The figure below shows these results.



What medical problems did participants have during the study?

This section is a summary of the medical problems participants had during the study that the doctors thought might be related to the study drugs. 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 drugs. 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 more information about the adverse reactions that happened in this study.

The results below are for 64 out of the 65 participants who began this study. Four of these 64 participants left the study, but researchers were able to study the results for these participants before they left.

How many participants had serious adverse reactions?

In this study, 7.8% of participants had serious adverse reactions that the researchers thought were related to the study drugs. This was 5 out of 64 participants.

The table below shows the serious adverse reactions that researchers thought were related to the study drugs.

Serious adverse reactions

	Durvalumab only (Out of 32 participants)	Durvalumab and tremelimumab (Out of 32 participants)	Total (Out of 64 participants)
Participants who had serious adverse reactions researchers thought were related to the study drugs	6.3% (2)	9.4% (3)	7.8% (5)

How many participants had adverse reactions?

In this study, 32.8% of participants had adverse reactions that the researchers thought were related to the study drugs. This was 21 out of 64 participants.

In this study, 6.3% of participants stopped treatment because of adverse reactions that the researchers thought were related to the study drugs. This was 4 out of 64 participants.

The table below shows the adverse reactions that researchers thought were related to the study drugs.

Adverse reactions			
	Durvalumab only (Out of 32 participants)	**Durvalumab and tremelimumab (Out of 32 participants)**	**Total (Out of 64 participants)**
Participants who had related adverse reactions	31.3% (10)	34.4% (11)	32.8% (21)

What adverse reactions did the participants have?

The most common adverse reactions that the researchers thought were related to the study drugs were tiredness, diarrhea, and low thyroid function.

These adverse reactions happened in 3 participants in either treatment group. There were other adverse reactions, but they happened in fewer participants.

The table below shows these adverse reactions.

Most common adverse reactions			
	Durvalumab only (Out of 32 participants)	**Durvalumab and tremelimumab (Out of 32 participants)**	**Total (Out of 64 participants)**
Tiredness	9.4% (3)	12.5% (4)	10.9% (7)
Diarrhea	6.3% (2)	12.5% (4)	9.4% (6)
Low thyroid function	0.0% (0)	9.4% (3)	4.7% (3)

How has this study helped participants and researchers?

The results presented here are for a single study. These results helped researchers learn about the safety of durvalumab and if it helps participants with pancreatic cancer.

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 1 study. Other studies may provide new information or different results.

Further clinical studies with durvalumab and tremelimumab in patients with metastatic pancreatic cancer are not currently planned.

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 **NCT02558894** into the search box called **"Other Terms"**. Then, click **"Search all studies"**.
- www.clinicaltrialsregister.eu. Once you are on the website, click **"Home and Search"**. Then, type **2015-002001-11** in the search box and click **"Search"**.

If you have questions about the results, please speak with the doctor, research nurse, or other team member at your clinic or hospital.

For more details about your study, please also refer to the informed consent form you signed before joining this study.

The full title of your study is: A Phase II Open-Label, Multi-Center Study of MEDI4736 Evaluated as Single Agent or in Combination with Tremelimumab in Patients with Metastatic Pancreatic Ductal Adenocarcinoma

The protocol number of your study is: D4198C00001

AstraZeneca AB, the sponsor of this study, has its headquarters in 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. It takes participants in many studies all around the world to advance medical science.

CISCRP

The Center for Information & Study on Clinical Research Participation (CISCRP) is a non-profit organization focused on educating and informing the public about clinical research participation. CISCRP is not involved in recruiting participants for clinical studies, nor is it involved in conducting clinical studies.

CISCRP • One Liberty Square, Suite 510 • Boston, MA 02109

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