Clinical Trial Results

AstraZeneca

Research Sponsor: AstraZeneca
Drugs Studied: Pramlintide
National Clinical Trial #: NCT02500979
Protocol #: D5570C00002
Study Date: August 2015 to August 2016
Short Study Title: A study to learn if pramlintide helps control blood sugar levels in participants who have type 1 diabetes and take insulin.

Thank you!

As a clinical study participant, you belong to a large community of participants around the world. You help researchers answer important health questions and discover new medical treatments.

Thank you for taking part in this clinical study for a drug called pramlintide. This drug has been approved to treat type 1 diabetes. You and all of the other participants helped researchers learn how pramlintide affects blood sugar levels and if pramlintide is safe to take when given with insulin in a pump.

AstraZeneca, the sponsor of this study, thanks you for your help and thinks it is important for you to know the results of your study. An independent non-profit organization called CISCRP prepared this summary of the study results for you with the help of a medical writing organization. We hope it helps you understand and feel proud of your important role in medical research. If you have questions about the results, please speak with the study doctors or staff at your study site.

CISCRP
THE CENTER FOR INFORMATION & STUDY ON CLINICAL RESEARCH PARTICIPATION

What's happened since my study ended?

Your study started in August 2015 and ended in August 2016. The study included 32 participants at 3 study sites in the United States. When the study ended, the sponsor reviewed the data and created a report of the results. This is a summary of that report.

Why was the research needed?

Even after a drug is approved, research must be done to show that it is safe and effective when it is used in new ways. The study drug, pramlintide, has been approved to treat type 1 diabetes. Patients with this disease have high levels of sugar in their bodies and need to take daily doses of insulin, a hormone made by the body that helps control blood sugar levels. But, some patients with type 1 diabetes still have problems lowering their blood sugar levels.

In this study, researchers wanted to learn if participants could have better control of their blood sugar levels by taking pramlintide and insulin together when given in 2 separate pumps. This is a new way of taking pramlintide, as it was previously given with insulin in a separate injection before each meal. Researchers also wanted to learn if pramlintide causes any medical problems when given in a pump.

Researchers compared pramlintide to a placebo. A placebo looks like the study drug but contains no real medicine. Researchers use a placebo so that they can compare the results of participants who get study drugs with the results of participants who get no medicine at all. Researchers wanted to know:

- Did pramlintide help lower blood sugar levels more than the placebo?
- Did pramlintide help participants in other ways?
- What medical problems did participants have after they took pramlintide?

What kind of study was this?

Your study was a "single-blind" study. This means that the study staff knew which drug the participants took, but the participants did not.

The study was also a "crossover" study. In a crossover study, all participants get the same treatments and tests, but the treatments are given in a random order.

Your study included 32 participants who were 23 to 70 years old and had type 1 diabetes. Out of the original 32 participants, all 32 participants got the pramlintide and insulin treatment. Only 28 of the 32 participants got the placebo and insulin treatment. This is because some participants left the study before it was completed.

What happened during the study?

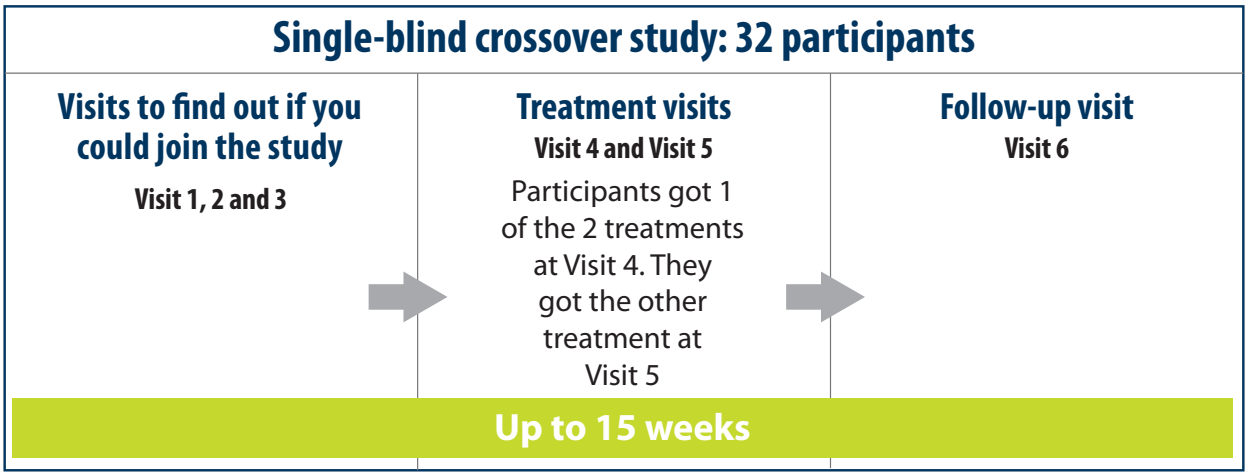
You and other participants were in the study for up to about 15 weeks.

To see if you could join the study, the study doctors did a physical examination by checking your height, weight, and temperature. They also took blood and urine samples and checked your heart health using an electrocardiogram, or ECG. The study doctors asked about your medical history, how you were feeling, and what medicines you were taking. These tests were repeated at every visit throughout the study.

If you are female, you had a blood test to make sure you were not pregnant.

During the study, participants visited their study site 6 times.

The figure below shows how the study was done.



During the follow-up period, study doctors did another physical examination, including checking your height, weight, and heart health. Study doctors asked again about your medical history, how you were feeling, and what medicines you were taking.

What were the study results?

Below is a summary of the results of some of the questions the researchers asked during this study. It is important to know that researchers and doctors look at the results of many studies to decide which medicines work best and are safest for patients. Further clinical studies with pramlintide are currently ongoing.

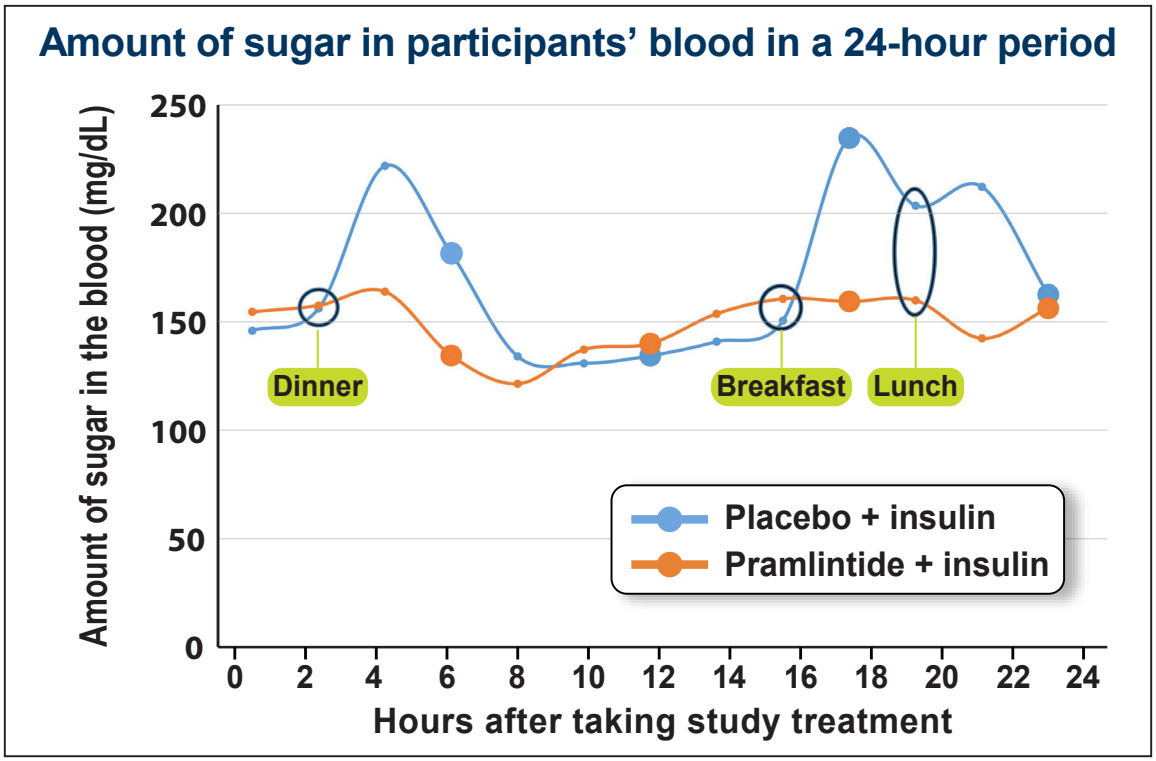
Did pramlintide help lower blood sugar levels more than the placebo?

Yes. Overall, researchers found that average blood sugar levels in participants were lower when they took pramlintide than when participants took the placebo. Researchers measured blood sugar levels in milligrams per deciliter of blood, or mg/dL. This is a way to measure the amount of sugar in the blood.

In a 24-hour period of time, researchers found that:

- When participants got pramlintide and insulin, they had about 152.2 mg/dL of sugar in their blood.
- When participants got the placebo and insulin, they had about 173.8 mg/dL of sugar in their blood.

The figure below shows the average amount of sugar participants had in their blood in a 24-hour period of time during this study. The larger dots on the line are when researchers measured participants' sugar levels, and meal times are circled.



Did pramlintide help participants in other ways?

Yes. Compared to when participants got the placebo and insulin, the researchers found:

- A decrease in the average amount of their blood sugar after all meals when participants got pramlintide and insulin.
- A decrease in the average amount of their blood glucagon, a hormone that raises blood sugar levels after meals, when participants got pramlintide and insulin.
- An increase in the average amount of time that participants had normal blood sugar levels between 70 and 180 mg/dL when participants got pramlintide and insulin.

What medical problems did participants have?

A lot of research is needed to know whether a drug causes a medical problem. Researchers keep track of all medical problems that participants have during the study. These medical problems are called "adverse events". They may or may not be caused by the study drug.

How many participants had medical problems during the study?

During this study, more participants had medical problems when they got pramlintide and insulin compared to when they got the placebo and insulin.

The table below shows the number of participants who had medical problems in the study. Three participants (9.4%) stopped taking the study drug because of medical problems. Two of the participants had nausea and vomiting, and 1 participant had high blood sugar. Researchers thought that the nausea and vomiting were caused by the pramlintide treatment, but the high blood sugar was not.

Medical problems in this study

	Pramlintide and insulin (Out of 32 participants)	Placebo and insulin (Out of 28 participants)
How many participants had medical problems?	22 (68.8%)	9 (32.1%)

How many participants had serious medical problems?

A medical problem is considered serious when it is life-threatening, causes lasting problems, or needs hospital care. In this study, no participants developed serious medical problems, and no participants died.

What were the most common non-serious medical problems in the study?

The table below shows the most common non-serious medical problems that happened in more than 1 participant in either treatment group in the study.

Most common non-serious medical problems in this study

Medical problem	Pramlintide and insulin (Out of 32 participants)	Placebo and insulin (Out of 28 participants)
Nausea	14 (43.8%)	2 (7.1%)
Headache	8 (25.0%)	1 (3.6%)
Vomiting	6 (18.8%)	0 (0.0%)
Low blood sugar levels	3 (9.4%)	0 (0.0%)
Tremor	1 (3.1%)	2 (7.1%)
Anemia	0 (0.0%)	4 (14.3%)

The low blood sugar category listed above was considered a medical problem. But, researchers were also interested in how many participants had even lower blood sugar.

When participants got pramlintide and insulin, 17 out of the 32 participants (53.1%) had lower blood sugar. When participants got the placebo and insulin, 10 out of the 28 participants (35.7%) had lower blood sugar.

Where can I learn more about the study?

If you have questions about the results, please speak with the study doctor or staff at your study site. You can find more information about your study online at www.clinicaltrials.gov/show/results/NCT02500979.

Official study title: A Randomized, Single-Blind, Two-Way Crossover, Placebo-Controlled Phase I Study to Compare the 24-hour Glucose Profile and Safety of Pramlintide and Insulin, Co-Administered in a Fixed-Dose Ratio, versus Placebo and Insulin in Patients with Type 1 Diabetes Mellitus with Inadequate Glycemic Control

AstraZeneca, the sponsor of this study, has its headquarters at 1800 Concord Pike, Wilmington, DE 19850.

The phone number for the AstraZeneca Information Center is 18772409479.

The results presented here are for a single study. Other studies may provide new information or different results. You should not make changes to your therapy based on the results of a single study without first consulting your healthcare professional.

Thank you

It is said that the greatest gift is one which is given anonymously, giving when you do not know whether you will get direct personal benefit.

This is the gift that you have given by taking part in a clinical study. It is a brave and selfless act, one that advances medical knowledge and benefits public health.

Thank you for the gift of your participation in clinical research.

CISCRP
THE CENTER FOR INFORMATION & STUDY ON CLINICAL RESEARCH PARTICIPATION

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 trials, nor is it involved in conducting clinical studies.

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