Clinical Trial Results

AstraZeneca

Research Sponsor:	AstraZeneca AB
Drugs Studied:	Exenatide (Bydureon®)
National Clinical Trial #:	NCT02533453
Protocol #:	D5551L00018
Study Date:	January 2016 to January 2017
Short Study Title:	A study to learn if exenatide is safe and how well it works in patients with type 2 diabetes

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 the drug exenatide. This is an approved drug for treating type 2 diabetes. You and all of the participants helped researchers learn if exenatide is effective and if it causes any medical problems.

AstraZeneca AB, 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 January 2016 and ended in January 2017. It included 110 participants at 16 study sites in South Korea. 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?

Researchers wanted to learn more about exenatide, a medicine used to treat type 2 diabetes. Type 2 diabetes is a disease in which the body does not use insulin normally. This makes the amount of sugar, or glucose, in the blood too high.

Exenatide was a new drug that works like a natural substance in the body called glucagon-like peptide-1, or GLP-1. GLP-1 helps keep blood sugar at healthy levels.

For people with type 2 diabetes, the GLP-1 in their body either doesn't work well or doesn't work at all. Exenatide helps the body release its own insulin when needed to reduce blood sugar level.

In this study, researchers wanted to see how safe exenatide is and how well it works in people with type 2 diabetes.

Researchers wanted to learn:

- How many and what type of medical problems did participants have when taking exenatide?
- How did the body react to exenatide treatment?

What kind of study was this?

Your study was an "open-label" study. This means that all of the participants, study doctors, and staff knew what treatment each participant got. In this study, all participants got exenatide.

Your study had 110 participants at 16 study centers in South Korea. All of the men and women who participated were between the ages of 22 and 72 years.

What happened during the study?

The study lasted 16 weeks for some participants and 28 weeks for other participants. There were 12 weeks of treatment during the 16-week study and 24 weeks of treatment during the 28-week study. Participants visited their study center up to 5 times. Of the 110 participants:

- 38 completed the 16-week study
- 63 completed the 28-week study
- 9 did not complete either study. Some of these participants completed enough of the study to be included in the results.

To see if you could join the study, study doctors did a physical examination and checked your pulse, blood pressure, and weight. They also took blood and urine samples for tests. One blood test was to check your blood sugar levels. Study doctors also asked about your medical history, how you were feeling, and what medicines you were taking.

All participants got 2 milligrams, or mg, of exenatide, given in a needle, once a week. During the study, there were:

- 4 visits for participants in the 16-week study
- 5 visits for participants in the 28-week study

During the study, your study doctor examined you regularly. This included asking about your medical history, how you were feeling, and what medicines you were taking. The study doctor also did a physical examination and checked your pulse, blood pressure, weight, and blood sugar level. You gave blood and urine samples for tests.

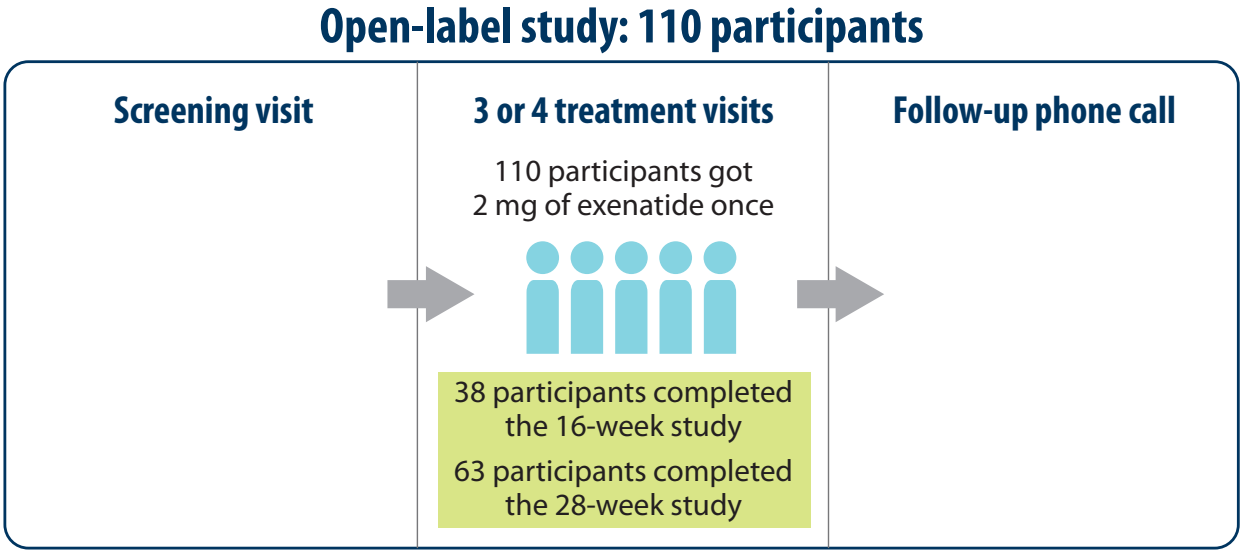
The study doctor or staff also called participants 3 times in the 28-week study and once in the 16-week study.

There were 4 weeks in between the first and second treatment visits. There were 8 weeks in between the second and third treatment visits.

During the 28-week study, there were 12 weeks in between the third and fourth treatment visits.

About 4 weeks after the end of the entire study, the study doctor or staff called you again to see how you were feeling.

The figure below shows how the study was done.



What were the study results?

Below is a summary of the results of some of the questions that researchers asked during this study. It is important to know that researchers look at the results of many studies to decide which medicines work best and are safest for patients. Further clinical studies with exenatide are not planned in Korea.

How many and what type of medical problems did participants have when taking exenatide?
A lot of research is needed to know whether a drug causes a medical problem. So, when new drugs are being studied, 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 in the study?
The results below are for 104 participants in this study.

Of the 104 participants, 55 (52.9%) had medical problems during the study.
Six participants (5.5%) stopped taking the study drug because of a medical problem.

How many participants had serious medical problems?
A medical problem is considered serious when it is life threatening, causes lasting problems, causes hospitalization, or is an important medical event. During the study, 4 of the 104 participants (3.8%) had serious medical problems. No participants died during the study. Researchers did not find any new safety problems.

The table below shows all serious medical problems that happened in this study.

Serious medical problem	Exenatide (out of 104 participants)
Inflammation of the pelvis	1 (1.0%)
Low blood sugar	1 (1.0%)
Stomach flu, also called acute gastroenteritis	1 (1.0%)
Tumor in cells that make hormones, called a neuroendocrine tumor	1 (1.0%)

What were the most common medical problems that were not serious?
There were 2 medical problems that were not considered serious and happened in at least 10% of participants in this study. Of the 104 participants:

- 16 (15.4%) had swelling around where the drug was injected.
- 15 (14.4%) had nausea.

How did the body react to exenatide treatment?
Researchers wanted to learn how the body reacted to exenatide treatment. To do this, they studied:

- if exenatide made participants feel better or not
- the average change in blood sugar levels over the last 2 or 3 months
- the average change in blood sugar levels without food
- the average change in blood pressure
- the average change in weight

Did exenatide make participants feel better or not?
Researchers gave participants a survey that asked how they felt about their disease. Participants were asked to note whether they felt their disease had "improved", had "slightly improved", was "unchanged", was "aggravated" or felt worse, or was "unable to evaluate" if they felt they could not give an answer. Overall, researchers found that most participants felt their diabetes had "improved" or had "slightly improved" at the end of their treatment with exenatide.

The table below shows the answers on the survey for the participants in each study.

Rating on survey	16-week study (out of 43 participants)	28-week study (out of 60 participants)
Improved	29 (67.4%)	55 (91.7%)
Slightly improved	7 (16.3%)	4 (6.7%)
Unchanged	5 (11.6%)	1 (1.7%)
Aggravated	1 (2.3%)	0 (0.0%)
Unable to evaluate	1 (2.3%)	0 (0.0%)

Average change in blood sugar levels over the last 2 or 3 months
Researchers measured the average change in blood sugar levels of participants over the last 2 or 3 months. To do this, researchers measured the percentage of blood cells that had attached themselves to the body's blood sugar. This measurement helps researchers estimate the blood sugar levels of participants over the last 2 or 3 months.

Researchers found the following:

- After 12 weeks of treatment during the 16-week study, the blood sugar level of participants had decreased by an average of 1.1%.
- After 24 weeks of treatment during the 28-week study, the blood sugar level of participants had decreased by an average of 1.3%.

Average change in blood sugar levels without food
Researchers also measured the average change in blood sugar levels after participants fasted, or did not eat any food. They measured the levels of sugar in the blood of participants in milligrams per deciliter of blood, or mg/dL.

Researchers found the following:

- After 12 weeks of treatment during the 16-week study, the blood sugar level of participants without food decreased by an average of 25.1 mg/dL.
- After 24 weeks of treatment during the 28-week study, the blood sugar level of participants without food decreased by an average of 40.7 mg/dL.

Average change in blood pressure

Researchers also measured the average change in the blood pressure of participants throughout the study. There are 2 types of blood pressure. Systolic blood pressure measures the pressure in the bloodstream when the heart is beating. Diastolic blood pressure measures the pressure in the bloodstream when the heart is resting. Both types are measured in millimeters of mercury, or mmHg. This is a way that researchers can measure pressure.

At the end of the study, researchers found that:

- the systolic blood pressure of participants decreased by an average of 3.35 mmHg
- the diastolic blood pressure of participants decreased by an average of 0.15 mmHg

Average change in weight

Researchers also measured the average change in the weight of participants throughout the study. At the end of the study, they found that the weight of participants decreased by an average of 0.95 kilograms, or kg.

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/NCT02533453

Official study title: A 12/24-weeks, open, multi-centre, phase IV study on safety and efficacy of 2mg exenatide once weekly (Bydureon) in patients with type 2 Diabetes Mellitus

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

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

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 trial. 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 (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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