Plain Language Summary of Study Results

Astellas is grateful to the people who took part in this clinical study. Thank you.

What was the study called?

A Study to Learn the Effect of Food on Mirabegron in Healthy Chinese People.

Why was the study needed?

Mirabegron is a medicine for overactive bladder. It is approved for use in China. However, the effect of food on mirabegron had not yet been studied in China. This study was done to provide this information.

The study medicine people took was mirabegron. People took 1 of 2 different doses of mirabegron after eating and after fasting. The level of mirabegron in their blood was measured over time. This helps researchers see what effect food has on the level of mirabegron in the blood.

The study started in September 2020 and ended in October 2020. The sponsor of this study (Astellas) reviewed all the study information and created a report of the results. This is a summary of that report.

What were the main questions the study helped answer?

- How much mirabegron stays in the blood of heathy Chinese people over time in the presence of food? And how does this compare when people fasted?
- It was also important to find out what medical problems people in this study had from mirabegron.

What kind of study was this and who took part in it?

This was an open-label study. That means that each person and the researchers knew that person took mirabegron.

Healthy Chinese men and women between 18 to 45 years of age were included in the study.

Body mass index (or BMI for short) is a measure of body fat in adults that is based on height and weight. The people in this study had a BMI that ranged from 19.0 to 24. Men weighed at least 50 kilograms. Women weighed at least 45 kilograms.

There were 24 people in the study. The following table has some additional information about them:

	Number of People **24**
Age Average age in this study was 26 years	
Sex Men Women	 20 4

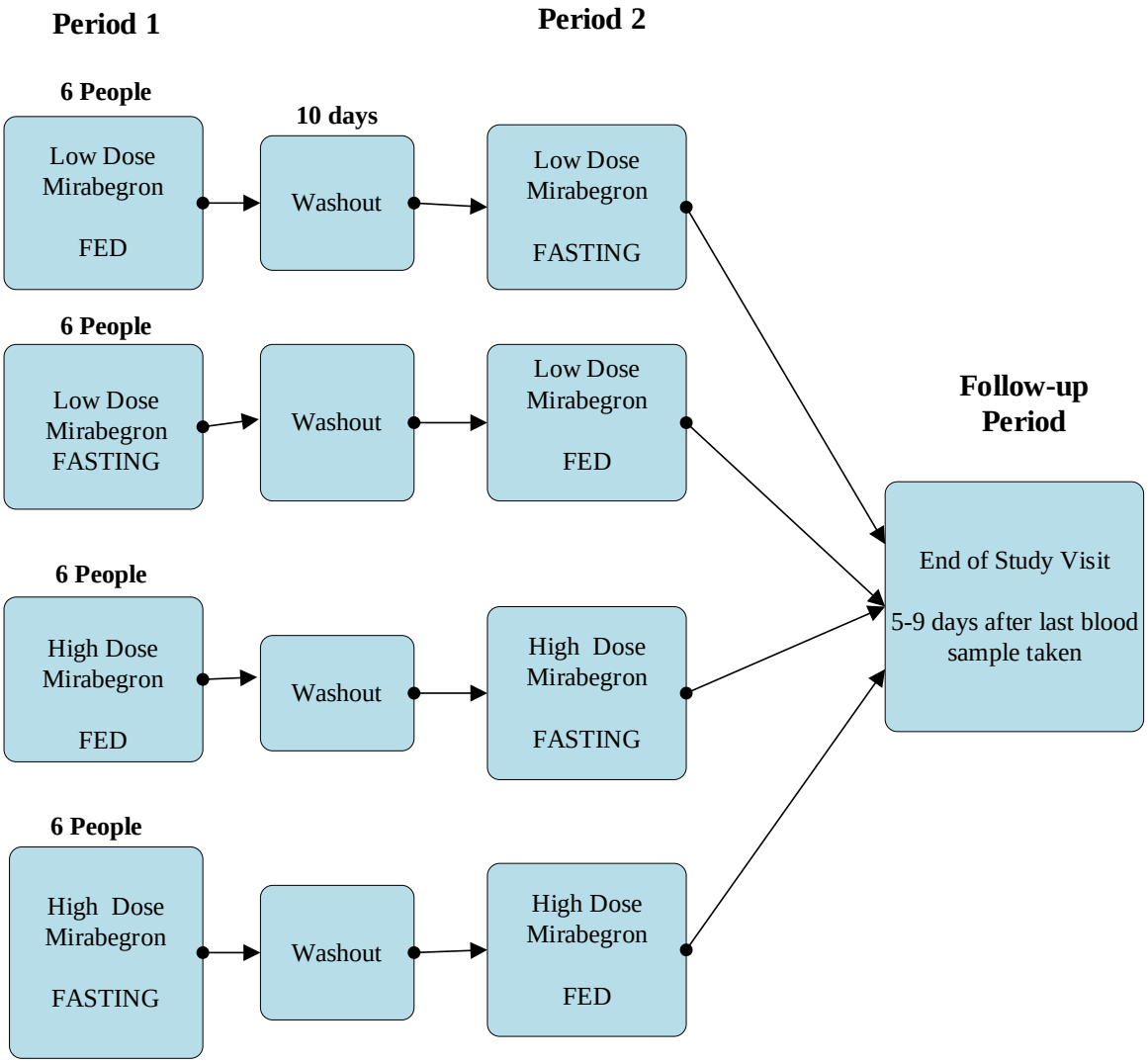
Where did the study take place?

This study took place at 1 clinic in China.

What happened during the study?

This was a 2-period study with a follow-up period. Each person in the study was in both periods. People took a single tablet of mirabegron in each period . This allowed the researchers to measure the level of mirabegron in the blood after they had a low-fat meal. And they measured again after the person had fasted. These groups were called 'Fed' and 'Fasting'. People took either high dose (50 milligram) mirabegron or low dose (25 milligram) mirabegron.

People were assigned to 1 of 4 treatment arrangements, by chance. For at least 10 days in between period 1 and period 2, people took no study medicine. This allowed the medicine to leave their body. These 10 days are called 'Washout'. People were checked for any medical problems throughout the study. And they were checked in the follow-up period after the study ended. The following chart shows what happened during the study:



What were the study results?

This study answered the question:

How much mirabegron stays in the blood of heathy Chinese people over time in the presence of food? And how does this compare when people fasted?

The researchers checked blood samples taken from 24 heathy Chinese men and women after they took a dose of mirabegron. They found that the level of mirabegron in people's blood was about 40% less when they took it after eating a low-fat meal. This is compared to when

they took it after fasting. This was true for both doses of mirabegron. This effect is consistent with the effect seen in healthy people in the US and Japan.

What adverse reactions did people have in this study?

A lot of research is needed to know whether a medicine causes a medical problem. So, when new medicines are being studied, researchers keep track of all medical problems that patients have while they are in the study. These medical problems are called "adverse events" and are recorded whether or not they might be caused by the treatment taken. An "adverse reaction" is any medical problem or "adverse event" that is judged by the study doctor to be possibly caused by a medicine or treatment used in the study.

5 people (20.8%, or 5 out of 24 people) had adverse reactions in this study.

The table below shows the most common adverse reactions experienced by people who took at least 1 dose of mirabegron in this study. The number of people with these adverse reactions are below:

Adverse Reaction	**Mirabegron (out of 24 people)**
Diarrhea	2 (8.3%)
Dizziness (or sensation of lightheadedness, unsteadiness, or giddiness)	2 (8.3%)

Did any of the people in this study have serious adverse reactions?

An adverse reaction is considered "serious" when it is life-threatening, causes lasting problems or needs hospital care.

No one had a serious adverse reaction in this study.

Where can I learn more about this study?

This document is a short summary of the main results from this study. You can find this summary and more information about this study at http://www.astellasclinicalstudyresults.com.

Please remember that researchers look at the results of many studies to find out how well medicines work and which adverse reactions they might cause. This summary only shows the results of this 1 study. Your doctor may help you understand more about the results of this study.

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