

Plain Language Summary of Study Results

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

What was the Study Called?

A Study of ELIGARD® in Hormone-dependent Prostate Cancer Patients. This was also known as the ELIGANT study.

Why was this Study Needed?

Prostate cancer growth is dependent on male hormones. An example of a male hormone is testosterone. Eligard® (also known as leuprolide acetate) is a prescription medicine for the treatment of prostate cancer. Eligard helps to lower testosterone levels. This stops or slows down the growth of prostate cancer.

Many clinical studies have been done using Eligard. Until this study, none were done in Asia. A study was needed to look at Eligard treatment in Asian men with prostate cancer.

The study started in June 2017 and ended in November 2019. 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?

This study kept track of how many medical problems the men had while receiving Eligard. The main question was how many of those medical problems were possibly caused by Eligard? Also, it was important to find out what those medical problems were.

What Kind of Study was this and Who Took Part in It?

This was an “open-label” study. That means that each man and the study doctors knew the study medicine the man took.

The Asian men in this study were diagnosed with prostate cancer. Their prostate cancer had been confirmed with tests. The man’s doctor had planned to start a new treatment. Men could be included in the study if their tests showed they still had prostate cancer, even after their prostate glands were removed or they had radiation. Men, who had not yet received treatment to reduce their hormone levels, could join the study. Men with metastatic prostate cancer could join if they had not received chemotherapy. Metastatic cancer means the cancer cells have spread from the prostate to other parts of the body.

Men with castrate resistant prostate cancer could not join the study. Castrate resistant prostate cancer means the man’s prostate cancer kept growing even when the amount of testosterone in the body was reduced to very low levels.

The Asian men in this study were between 50 and 90 years of age.

What Happened during the Study?

During the study, the doctor did a check-up of the men at several study visits. At the first visit, men were checked to see if they could be in the study. Those who could be in the study received an injection under the skin of 22.5 milligrams of Eligard every 3 months. The study medicine was continuously released over each 3 month period. Information on the men was gathered every 3 months for 18 months. A man was free to leave the study for any reason, at any time.

Where did the Study Take Place?

This study took place at 20 clinics in 8 countries in Asia. 107 men took at least 1 dose of study medicine. 106 of those men provided information on any medical problems. Follow up information on medical problems was not provided by 1 man from Taiwan.

Clinic Location	Number of Men
Greater China Region	24
Taiwan	20
Hong Kong	4
Malaysia	21
Singapore	20
Philippines	17
Vietnam	15
Thailand	6
Indonesia	4

What Were the Study Results?

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 people 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.

How many men in this study had adverse reactions?

14 men (13.2%, or 14 out of 106 men) had adverse reactions in this study.

The only adverse reaction which occurred in more than 1 man was feeling hot for a brief moment (hot flush). 5 men (4.7%, or 5 out of 106) had hot flushes during this study.

Did any of the men 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.

2 men (1.9%, or 2 out of 106 men) experienced serious adverse reactions.

9 of the total 107 men passed away during the study. None of the deaths were because of the study medicine.

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 online 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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