

Summary of Results for Laypersons

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

What was the Study Called?

A Phase I, Open-label, Randomized, Parallel, Relative Bioavailability Study Comparing a Capsule and a Tablet Formulation of Enzalutamide Following Multiple Once Daily Doses of 160 mg Enzalutamide in Male Subjects with Prostate Cancer.

Why was this Study Needed?

Prostate cancer growth is dependent on male hormones or “androgens.” An example of an androgen is testosterone. Enzalutamide is a medicine used to treat men with prostate cancer. It blocks the effect of androgens. For a time, this stops or slows down the growth of prostate cancer. At the time of this study, enzalutamide was available as a 40-mg capsule. Four capsules had to be taken at once to reach the daily dose of 160 mg. Therefore, there was the need to study a new formulation. The new formulation was a 160-mg tablet taken once a day.

This was a phase 1 study. These studies look at what the body does to the study medicine and what the study medicine does to the body. Phase 1 studies often involve healthy participants. These studies may also involve participants with certain health conditions. This study was conducted in patients with prostate cancer. They took enzalutamide tablets or capsules. This study looked at the amount of enzalutamide that becomes available in the blood. The study assessed if that amount was the same after the men took 4 capsules or 1 tablet once a day for 56 days. It was also important to find out what unwanted effects the men had from the study medicines.

The study started in December 2012 and ended in October 2013. When the study ended, 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 Kind of Study was this and Who Took Part in It?

This was an “open-label” study. This means that each patient and the study doctors knew which study medicine that patient took (enzalutamide tablets or capsules).

This study included men 18 years and older who had prostate cancer that was growing, spreading or getting worse. During the study, they were taking hormone treatment that blocks the effect of androgens. Or they had been castrated. They were active or could perform light daily activities. They were expected to live for at least 6 months.

During the study, the study 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. Men who could be in the study were picked for a treatment (enzalutamide tablets or capsules) by chance alone.

- Capsule group: Enzalutamide 160 mg (four 40-mg capsules) once a day.
- Tablet group: Enzalutamide 160 mg (1 tablet) once a day.

Men took study medicine for up to 57 days.

This study took place at 4 clinics in the US. 27 men between the ages of 57 and 92 years were in the study. They took at least 1 dose of study medicine (enzalutamide capsules or tablets).

What Were the Study Results?

This study in men with prostate cancer looked at the amount of enzalutamide that becomes available in the blood. The study assessed if that amount was the same after the men took 4 capsules or 1 tablet once a day for 56 days. The men took their dose on day 56 on an empty stomach. This was to make sure that food could have no effect on the amount of study medicine in the blood. Next, the peak level and overall amount of enzalutamide in the blood were measured.

Compared to capsules, the peak level was 18% lower with tablets.

Compared to capsules, the overall amount was similar with tablets.

The study showed that the amount of enzalutamide in the blood was comparable. It did not matter whether the men took 4 capsules or 1 tablet once a day for 56 days.

What Adverse Reactions did Patients Have?

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.

The table below shows the most common adverse reactions experienced by men who took at least 1 dose of study medicine in this study.

Adverse Reaction	Enzalutamide (out of 27 men)
Any adverse reaction	19 (70.4%)
Diarrhea	5 (18.5%)
Fatigue or tiredness	5 (18.5%)
Constipation	3 (11.1%)
Lack of enough red blood cells (anemia)	3 (11.1%)

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

One man (3.7%, or 1 out of 27 men) experienced 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 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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