

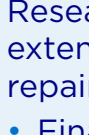
Comparing quality of life ratings from patients with advanced prostate cancer and changes in specific DNA repair genes taking talazoparib plus enzalutamide versus a placebo plus enzalutamide: Final results from the TALAPRO-2 study

The full title of this abstract is: Final patient-reported outcomes (PROs) in men with metastatic castration-resistant prostate cancer (mCRPC) and homologous recombination repair (HRR) gene alterations receiving initial treatment with talazoparib (TALA) + enzalutamide (ENZA) vs placebo (PBO) + ENZA in the TALAPRO-2 study

VIEW ABSTRACT

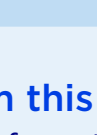
Please note that this summary only contains information from the scientific abstract:

[View Scientific Abstract >](#)



Date of summary:
May 2025

Study number: NCT03395197



Study start date: December 2017
Estimated study end date: December 2025

For more information on this study, go to:
<https://clinicaltrials.gov/ct2/show/NCT03395197>

KEY TAKEAWAYS

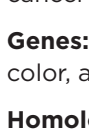
What are the key takeaways from this study?

Researchers looked at updated results from the TALAPRO-2 study over an extended period to see how patients with changes in homologous recombination repair or HRR genes rated quality of life with treatment.

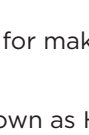
- Final results showed that patients who took **talazoparib** plus **enzalutamide** and patients who took a **placebo** plus **enzalutamide** tended to have a similar overall quality of life.
- Patients who took **talazoparib** plus **enzalutamide** rated some of their functioning and symptoms a little more positively than patients who took a **placebo** plus **enzalutamide**.

PHONETICS

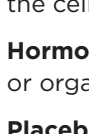
Find out how to say medical terms used in this summary



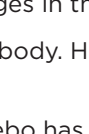
Enzalutamide
< EN-zuh-LOO-tuh-mide >



Placebo
< pluh-SEE-boh >



Metastatic
< meh-tuh-STÄ-tik >



Talazoparib
< TÄ-luh-ZOH-puh-rib >

GLOSSARY

Cancer: abnormal cells that grow and divide without control and may spread to other parts of the body.

DNA: the molecule inside cells that carries genetic information and passes it on from one generation to the next.

Enzalutamide: an oral medicine that stops male sex hormones, like testosterone, from helping prostate cancer cells grow.

Genes: part of your DNA that has instructions for making proteins. Genes give you your height, natural hair color, and eye color.

Homologous recombination repair genes: known as HRR genes for short, are a group of genes that direct the cell to find and repair DNA damage. Changes in these genes can make it hard for the cell to repair DNA.

Hormone: a substance made by glands in the body. Hormones control the actions of specific kinds of cells or organs.

Placebo: sometimes called a sugar pill, a placebo has no active ingredients. It looks the same as the medicine that is being tested.

Prostate: a male reproductive gland that sits below the bladder.

Talazoparib: an oral medicine that targets some types of cancer cells and stops them from growing and spreading.

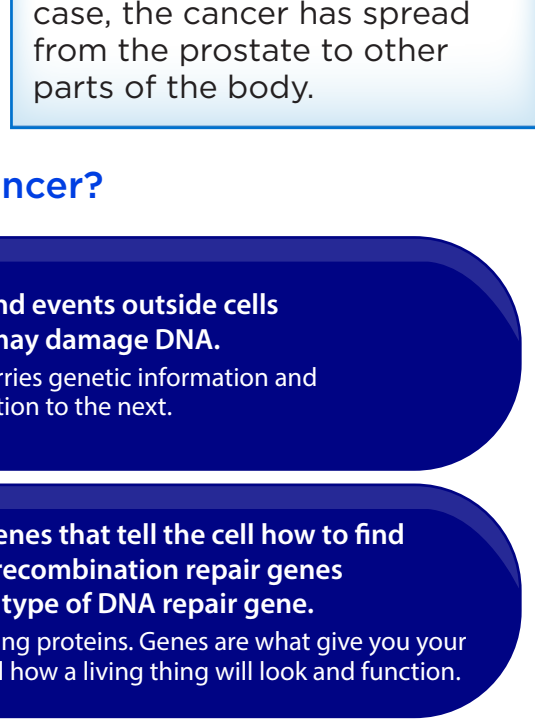
Tumor: a growth or lump of cancer cells.

INTRODUCTION

What does this study look at?

What is metastatic castration-resistant prostate cancer?

- Metastatic castration-resistant prostate cancer** is called **mCRPC** for short. It is cancer that starts in the prostate gland and spreads to other parts of the body, such as bones and lymph nodes.
- Castration-resistant means the prostate cancer does not respond to medicines that lower levels of testosterone in the blood.
 - Testosterone is a male sex hormone. Testosterone can help prostate cancer grow.



What genetic changes occur in prostate cancer?



Every day, processes inside cells and events outside cells (like radiation from the sun) may damage DNA. DNA is a molecule inside your cells that carries genetic information and passes it on from one generation to the next.



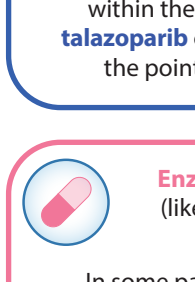
DNA is important, so there are DNA repair genes that tell the cell how to find and repair DNA damage. Homologous recombination repair genes (known as HRR genes for short) are a type of DNA repair gene. A gene is part of your DNA and has instructions for making proteins. Genes are what give you your height, natural hair color, and eye color. Proteins control how a living thing will look and function.



Some patients with prostate cancer have changes in HRR genes within their tumor, and therefore it is hard for the cells inside the tumor to repair DNA. A tumor is a growth or lump of cancer cells.



At the same time, these changes in HRR genes may also make cancer cells more responsive to some medicines that treat cancer.



- Prostate cancer tumors with changes in HRR genes may spread and grow faster than tumors without changes in HRR genes.
- Testing for changes in HRR genes within the patients' tumors may help their doctor understand the likely course of their disease and which treatment the patients may benefit from.

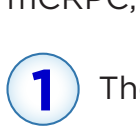
Why combine talazoparib with enzalutamide to treat mCRPC?

Talazoparib and **enzalutamide** are two different cancer medicines.



Talazoparib targets and kills cells that have changes in HRR genes.

Some patients with mCRPC have changes in HRR genes within their tumors. For these patients, treatment with **talazoparib** can cause their tumors to decrease or shrink to the point that they can no longer be seen on scans.



Enzalutamide stops male sex hormones (like testosterone) from helping prostate cancers grow. In some patients who have mCRPC, **enzalutamide** can increase the length of time they live. **Enzalutamide**, combined with medicines to lower testosterone levels in the blood, is approved to treat patients with mCRPC in some countries.



Talazoparib may help cancer cells become more responsive to **enzalutamide**.

Enzalutamide may also make the cancer cells more responsive to **talazoparib**. Therefore, researchers are studying the combination of **talazoparib** plus **enzalutamide**, which may help the two medicines work together more effectively in patients with changes in HRR genes within their tumors. Researchers are also studying the combination of **talazoparib** plus **enzalutamide** in patients without changes in HRR genes within their tumors.

Talazoparib in combination with **enzalutamide** is approved in the United States to treat patients with mCRPC and changes in HRR genes.

Talazoparib in combination with **enzalutamide** is approved in the European Union to treat patients with mCRPC with or without changes in HRR genes who cannot receive chemotherapy.

What does this summary describe?

Researchers looked at updated results from the TALAPRO-2 study over an extended period. Researchers wanted to see how patients with changes in HRR genes rated their quality of life.

This study describes how treatment with either **talazoparib** plus **enzalutamide** or placebo plus **enzalutamide**, as the first medicine patients took for their mCRPC, affected:

- The patients' quality of life, functioning, symptoms, and pain.
- The amount of time from the start of the study to when the patients' quality of life, symptoms, and pain clearly got worse.

Researchers wanted to find out...

- How did treatment with **talazoparib** plus **enzalutamide** affect patients' quality of life compared with a **placebo** plus **enzalutamide**?



STUDY DETAILS

Who took part in this study?

- All patients:



- Had mCRPC with changes in HRR genes.
- Had their prostate cancer get worse despite previous treatment at an earlier stage of their prostate cancer.
- Were at least 18 years old, or at least 20 years old if they lived in Japan.
- Could walk and do light activities.

All patients in TALAPRO-2 took **enzalutamide** with either **talazoparib** or a **placebo**



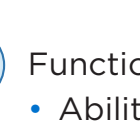
Half were randomly assigned to take **talazoparib 0.5 milligrams** plus **enzalutamide 160 milligrams** per day



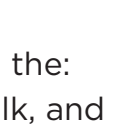
Half were randomly assigned to take a **placebo** plus **enzalutamide 160 milligrams** per day

Neither the patients in the study nor the doctors caring for them knew whether the patients took **talazoparib** or a **placebo**.

Of all the patients in the study who rated their quality of life at the start of the study and at least one more time during the study, there were:



197 patients
took **talazoparib** plus **enzalutamide**



394 patients
from the TALAPRO-2 study



197 patients
took a **placebo** plus **enzalutamide**

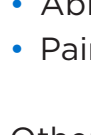
RESULTS

What were the results of this study?

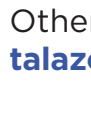
Throughout the study, researchers used surveys to ask patients to rate:

- Their overall health and quality of life
- How well they were able to function
- Their symptoms, including pain

1 Quality of life was similar between patients who took talazoparib plus enzalutamide and patients who took a placebo plus enzalutamide.



Patients were asked to rate their overall health and quality of life, how well they were able to function, and their symptoms.



Functioning included the:

- Ability to move, walk, and lift objects
- Ability to do normal daily activities and hobbies
- Patient's mood: If the patient felt tense, irritable, worried, or depressed
- Ability to concentrate and remember things
- Patient's family and social life



Symptoms included:

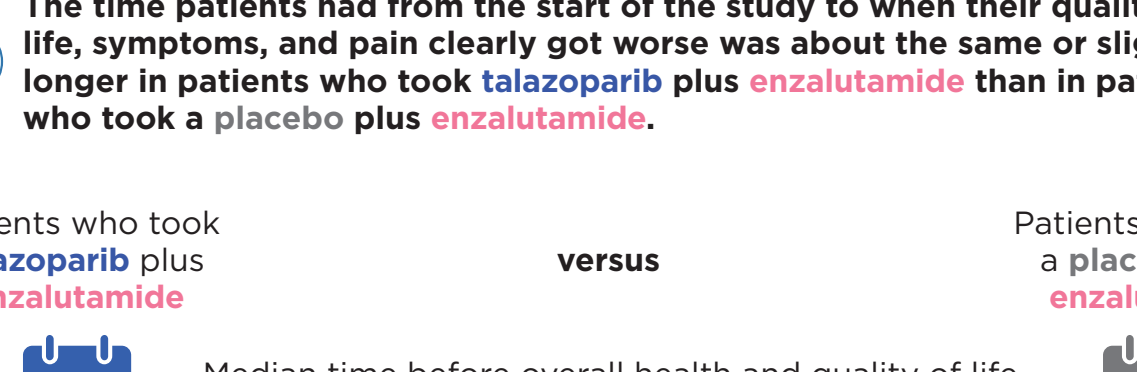
- Fatigue (extreme tiredness)
- Nausea and vomiting
- Pain

Patients who took **talazoparib** plus **enzalutamide** rated some of their functioning and symptoms a little more positively than patients who took a **placebo** plus **enzalutamide**:

- Ability to move, walk, lift objects
- Ability to concentrate and remember things
- Pain symptoms

Other functions and symptoms were similar for patients who took **talazoparib** plus **enzalutamide** compared with a **placebo** plus **enzalutamide**.

Researchers also looked at the **median** time from the start of the study to when the patients rated their quality of life and symptoms as clearly worse.



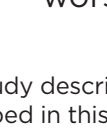
In this case, it means that half of the patients had a longer time before their quality of life got clearly worse than the median, and half had a shorter time before their quality of life got clearly worse than the median.

2 The time patients had from the start of the study to when their quality of life, symptoms, and pain clearly got worse was about the same or slightly longer in patients who took talazoparib plus enzalutamide than in patients who took a placebo plus enzalutamide.

Patients who took **talazoparib** plus **enzalutamide**

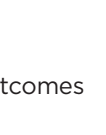
versus

Patients who took a **placebo** plus **enzalutamide**



34.2 months

Median time before overall health and quality of life clearly got worse



22.1 months

Compared with patients who took a **placebo** plus **enzalutamide**, those who took **talazoparib** plus **enzalutamide**:

- Had a similar length of time before their urinary symptoms from prostate cancer got worse. Urinary symptoms may include:
 - An increased need to pee
 - Straining while you pee
 - A feeling that your bladder has not fully emptied

Researchers asked patients to rate their level of pain at its worst in the last 24 hours.

- Compared with patients who took a **placebo** plus **enzalutamide**, those who took **talazoparib** plus **enzalutamide** had a longer time before their worst pain got clearly worse.

The study described is still ongoing, therefore the final outcomes of this study may differ from the outcomes described in this summary.

This summary reports the results of a single study. The results of this study may differ from those of other studies. Health professionals should make treatment decisions based on all available evidence and not just on a single study.

Talazoparib plus enzalutamide is used to treat the condition under study that is discussed in this summary. Approval varies by country; please check with your local provider for more details.

CONCLUSIONS

What were the main conclusions of this study?

- Final results from the TALAPRO-2 study showed that over a longer period and compared with those who took a **placebo** plus **enzalutamide**, patients with changes in HRR genes who took **talazoparib** plus **enzalutamide** as the first treatment for their mCRPC tended to have:
 - Similar overall quality of life
 - More positive physical and cognitive functioning
 - Lesser pain symptoms
 - A longer time before their pain got clearly worse

- Overall, **talazoparib** plus **enzalutamide** maintained the quality of life for patients with changes in HRR genes, supporting previous findings from earlier stages of the study.

MORE INFORMATION

Who sponsored this study?

This study was sponsored by **Pfizer Inc.**, and **Astellas Pharma Inc.** provided **enzalutamide**.

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Pfizer thanks everyone who took part in the study.

Where can I find more information?

For more information on this study, please visit:

[View Scientific Abstract >](#)

<https://clinicaltrials.gov/ct2/show/NCT03395197>

For more information on prostate cancer or clinical trials in general, please visit:

<https://www.cancer.net/cancer-types/prostate-cancer>

<https://www.clinicaltrials.gov/ct2/about-studies/learn>

<http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/what-clinical-trials-are>

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