

The EMBARK trial: Is it possible for patients with prostate cancer to maintain low prostate-specific antigen levels and have their testosterone levels return to normal while off treatment?

The full title of this abstract is: Are long-term remissions possible with hormonal therapy only? Post hoc analysis of EMBARK examining sustained prostate-specific antigen (PSA) <0.2 ng/mL despite testosterone (T) recovery after treatment (tx) suspension

VIEW ABSTRACT

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

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Date of summary:
February 2026

Study number: NCT02319837

Study start date:
December 2014

Estimated study completion date:
September 2026

For more information about the EMBARK clinical trial, go to: <https://clinicaltrials.gov/study/NCT02319837>

KEY TAKEAWAYS

What are the key takeaways from this study?

- The EMBARK trial included patients with prostate cancer and quickly rising prostate-specific antigen (PSA) levels after definitive therapy. Rising PSA levels after definitive therapy may suggest that prostate cancer has returned.
- This study looked at patients treated with enzalutamide and androgen deprivation therapy (ADT), placebo and ADT, or enzalutamide alone who had a treatment holiday (a break from treatment).
 - Patients who reached a PSA level of less than 0.2 nanograms per milliliter after 9 months of treatment took a treatment holiday.
 - Researchers looked at PSA and testosterone levels measured after taking a treatment holiday.
- At 3 years after a treatment holiday, the chances that PSA levels remained at less than 0.2 nanograms per milliliter despite testosterone recovery to normal levels (more than 250 nanograms per deciliter) were:
 - 1 in 25 for patients treated with enzalutamide and ADT,
 - 1 in 100 for patients treated with placebo and ADT, and
 - 1 in 100 for treated with enzalutamide alone.
- These results suggest that it is possible for patients treated with enzalutamide and ADT for 9 months to have PSA levels that remain at less than 0.2 nanograms per milliliter and have testosterone recovery to normal levels for a long time after taking a treatment holiday.

PHONETICS

Find out how to say medical terms used in this summary

- Androgen** < AN-droh-jen >
- Enzalutamide** < EN-zuh-LOO-tuh-mide >
- Prostate cancer** < PROS-tayt KAN-ser >

INTRODUCTION

What was this study about?

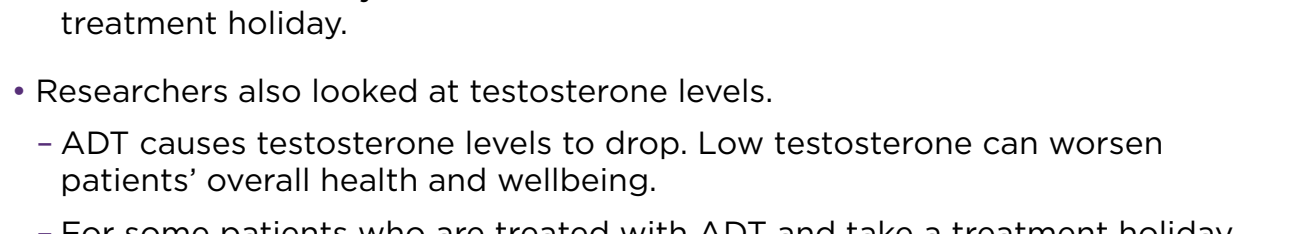
- Prostate cancer** is a cancer that occurs in the prostate. It is one of the most common cancers in males.
 - The prostate is part of the male body that helps make semen.
 - Cancer is a disease where abnormal cells multiply and form a tumor.
- Treatment that aims to cure a condition or provide long-term relief from it is known as **definitive therapy**. In prostate cancer, definitive therapy may be done as:
 - surgery to remove the prostate and some of the tissue around it
 - radiation treatment to kill cancer cells in the prostate
 - Radiation treatment uses high-energy waves to kill cancer cells. Radiation may come from a machine outside of the body or from radioactive material placed inside the body near the cancer cells.

- For some patients with prostate cancer, **PSA levels** rise after definitive therapy. This suggests that the cancer has come back.
 - PSA is a protein produced by normal prostate cells. Small amounts of PSA are usually found in the blood.
 - A low PSA level after treatment can be a sign that the treatment is keeping the cancer under control.

What treatments did patients in this study receive?

- Most prostate cancers need male sex hormones, called androgens, to grow.
 - Testosterone is an example of an androgen. Testosterone is a hormone that controls the development of the male reproductive organs and male traits, like body hair and voice.
- Treatments that lower androgen levels are known as **ADT**. ADT may be carried out as surgery or given as medicine.
 - In the EMBARK trial, the medicine **leuprolide** was used as **ADT**.
- Enzalutamide** is a type of hormone treatment that can slow or stop androgens, such as testosterone, from making prostate cancer grow.
- A **placebo** looks like the study treatment but does not contain any active ingredients.

Patients in the EMBARK trial were put in one of three groups and were treated with:



- If a patient's PSA levels were very low (less than 0.2 nanograms per milliliter) after 9 months of treatment, they took a treatment holiday.
 - A treatment holiday is a break from treatment. Patients were allowed one treatment holiday.
- Researchers also looked at testosterone levels.
 - ADT causes testosterone levels to drop. Low testosterone can worsen patients' overall health and wellbeing.
 - For some patients who are treated with ADT and take a treatment holiday, testosterone levels increase and return to normal levels. This is called **testosterone recovery**.

What was the aim of the research reported in this summary?

- The researchers carried out a **post hoc analysis**. This means that they looked at the data in a new way after the study had been done.
- Researchers wanted to see what were the chances that PSA levels remained at **less than 0.2 nanograms per milliliter** despite testosterone recovery after taking a treatment holiday in patients treated with:
 - enzalutamide and ADT,
 - placebo and ADT, or
 - enzalutamide alone.
- The researchers looked at 3 groups of testosterone recovery:
 - increased to more than 175 nanograms per deciliter;
 - increased and returned to normal levels (more than 250 nanograms per deciliter); and
 - increased and returned to the levels before the start of study.

Nanogram per milliliter: A nanogram is one billionth of a gram and a milliliter is one thousandth of a liter.

Researchers wanted to find out...

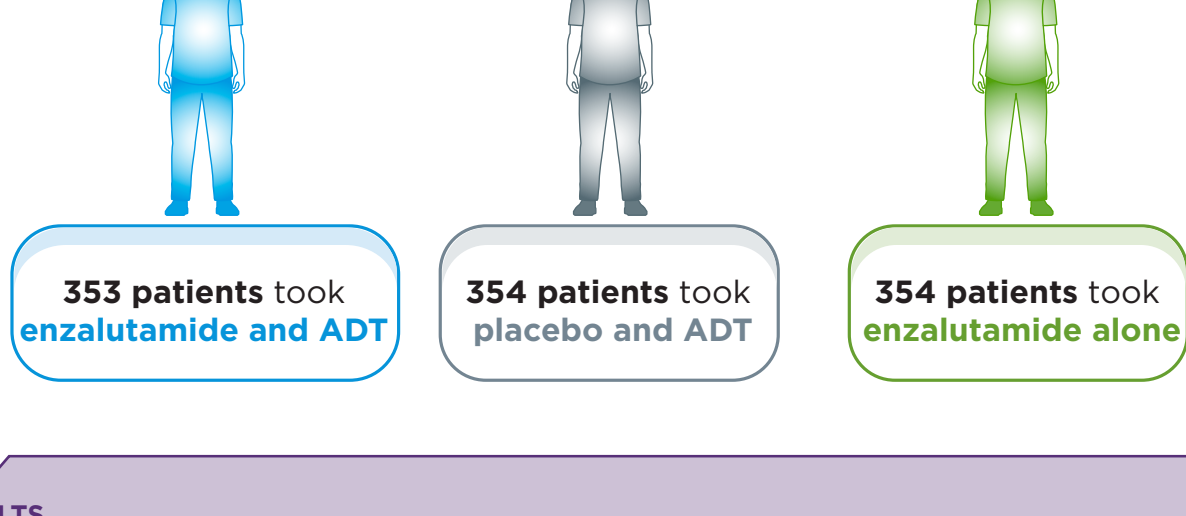
- For patients who took a treatment holiday,
 - how many patients continued to have low PSA levels for 3 years and had their testosterone return to normal levels?
 - did the chance of PSA levels remaining low differ by treatment?

STUDY DETAILS

Who took part in this research?

- This research included patients from the EMBARK trial who took at least one dose of the study drug.

Patients from the EMBARK trial who took at least one dose of the study drug



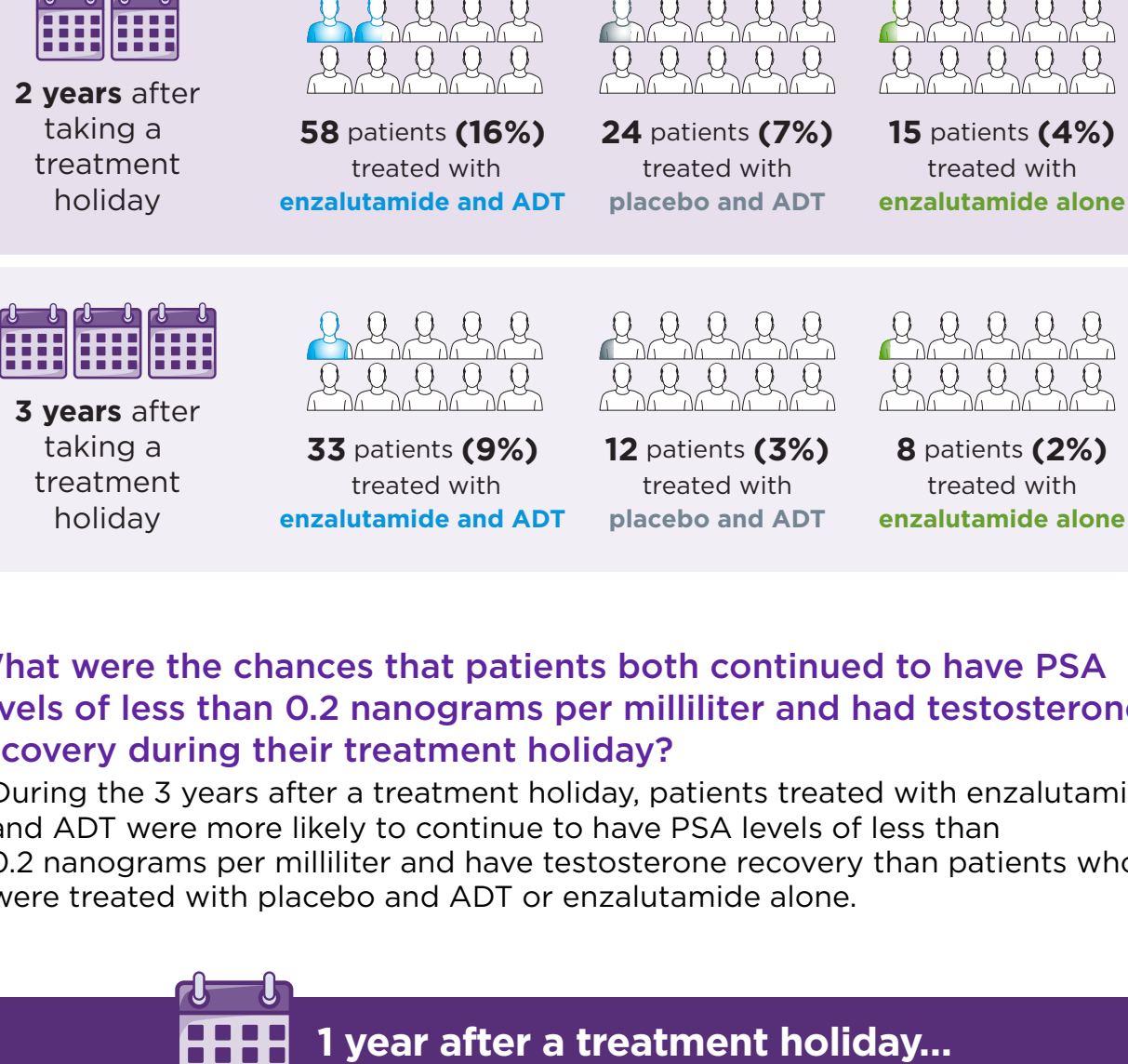
RESULTS

What were the results of this research?

What were the chances that PSA levels remained at less than 0.2 nanograms per milliliter during a treatment holiday?

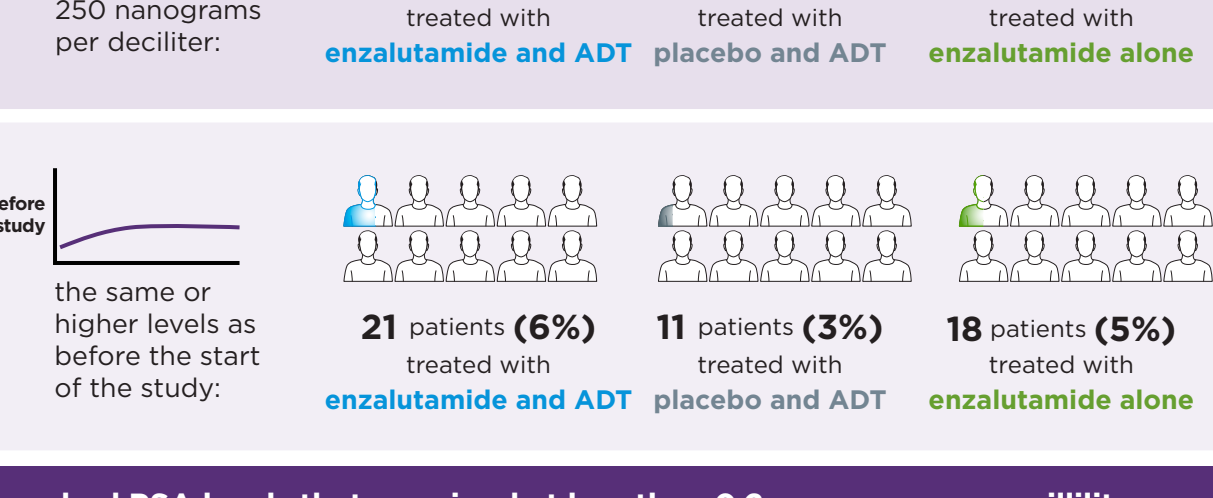
- During a treatment holiday, patients treated with enzalutamide and ADT were more likely to have PSA levels of less than 0.2 nanograms per milliliter compared with patients treated with placebo and ADT or enzalutamide alone.

During a treatment holiday, PSA levels remained at less than 0.2 nanograms per milliliter in...

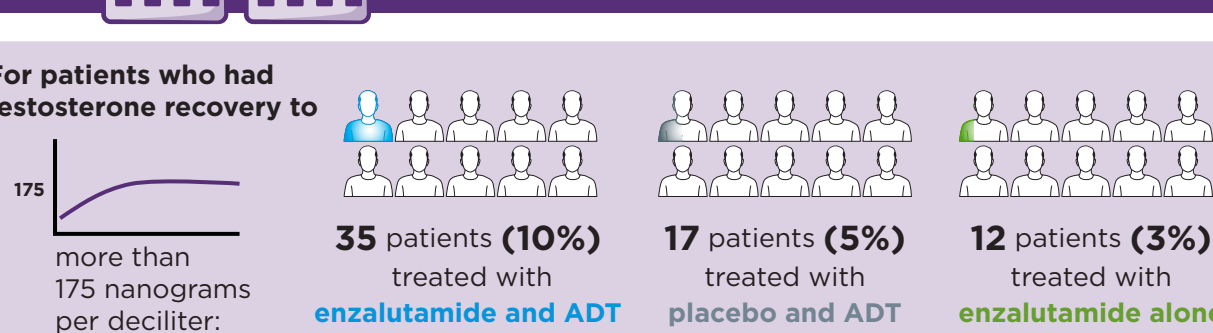


What were the chances that patients both continued to have PSA levels of less than 0.2 nanograms per milliliter and had testosterone recovery during their treatment holiday?

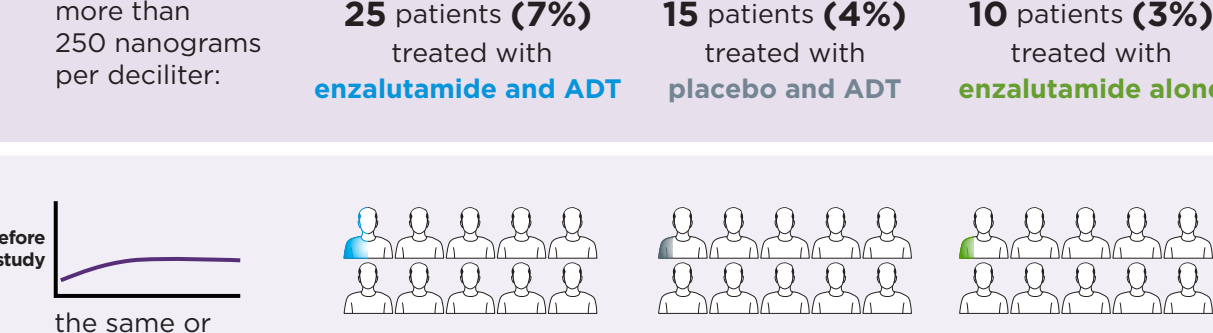
- During the 3 years after a treatment holiday, patients treated with enzalutamide and ADT were more likely to continue to have PSA levels of less than 0.2 nanograms per milliliter and have testosterone recovery than patients who were treated with placebo and ADT or enzalutamide alone.



had PSA levels that remained at less than 0.2 nanograms per milliliter.



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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, not on the results of a single study. Enzalutamide is approved to treat the condition that is discussed in this summary. The study described is still ongoing, therefore the final outcomes of this study may differ from the outcomes described in this summary.

CONCLUSIONS

What are the conclusions of this study?

- During the 3 years after a treatment holiday, the chances that patients continued to have PSA levels of less than 0.2 nanograms per milliliter and testosterone recovery to normal levels (more than 250 nanograms per deciliter) were:
 - 1 in 25 for patients treated with enzalutamide and ADT,
 - 1 in 100 for patients treated with placebo and ADT, and
 - 1 in 100 for treated with enzalutamide alone.
- These results suggest that it is possible for patients treated with enzalutamide and ADT for 9 months to have PSA levels that remain at less than 0.2 nanograms per milliliter and have testosterone recovery to normal levels for a long time after taking a treatment holiday.

MORE INFORMATION

Who sponsored this study?

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

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The sponsors thank everyone involved in this study.

Where can I find more information?

For more information about the EMBARK clinical trial, please visit: <https://clinicaltrials.gov/study/NCT02319837>

For more information on clinical trials in general, please visit: <https://www.clinicaltrials.gov/study-basics/learn-about-studies> and <http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/what-clinical-trials-are>

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