EvoPAR
Prostate 01

A new clinical study in prostate cancer

A simple guide to help you decide if EvoPAR-Prostate01 is right for you

Study code: D9723C00001 Version no.: 1.0 Date: 09/07/2023 US-enUS

Thank you for considering taking part in this study.
The findings may help people diagnosed
with prostate cancer in the future.

What is EvoPAR-Prostate01?

It is a clinical study looking at whether a new experimental treatment called AZD5305 can help men with a certain type of prostate cancer.

What is a clinical study?

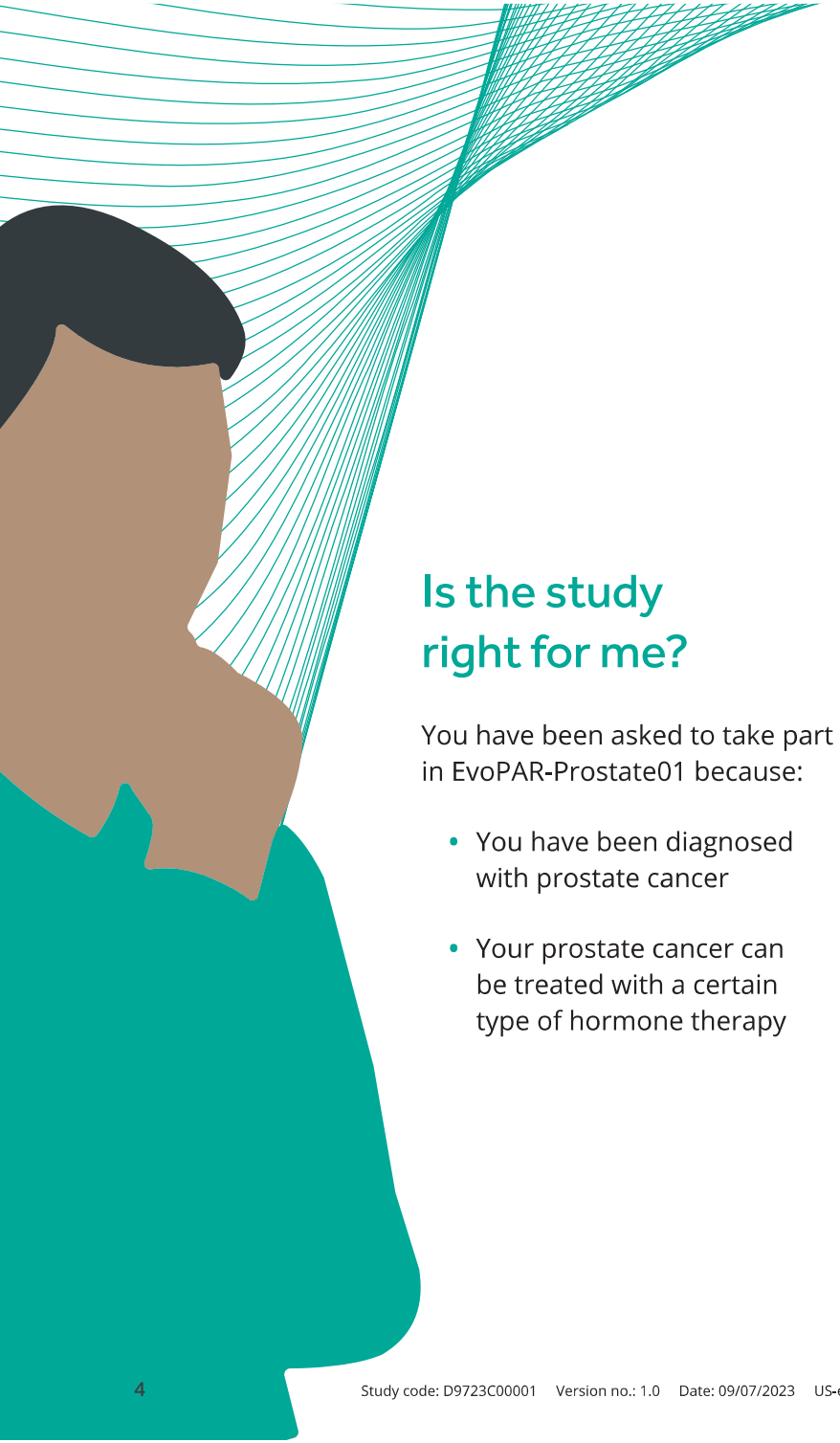
It is a type of research that explores whether an experimental treatment is safe and works in humans. It is just one part of a long, careful research process.

Clinical studies are used to help understand if a new treatment works better than the standard treatment, or what side effects it might have.

This pamphlet has been developed to help you understand a bit more about the EvoPAR-Prostate01 study and decide whether the study is right for you.

REMEMBER YOU CAN...

...ask your doctor or the study team questions at any time!



Is the study right for me?

You have been asked to take part in EvoPAR-Prostate01 because:

- You have been diagnosed with prostate cancer
- Your prostate cancer can be treated with a certain type of hormone therapy

There are other criteria to check if the study is the best fit for you. Your doctor can discuss these with you in more detail.

They will also be able to answer any questions you may have about the study and help you decide whether taking part is right for you.

If you decide you would like to join EvoPAR-Prostate01, you will be asked to sign an **Informed Consent Form (ICF)**.

This says you understand what the study involves and agree to take part. You will have different ICFs to sign to consent to different parts of this study.

What happens in EvoPAR-Prostate01?

During the study, you will be closely monitored by the study team. If you decide to join, there are 4 key periods of this study:

1. HRRm biomarker testing
Looking at some features of your cancer using blood and tumor samples

2. Main screening
Making sure the study is right for you and you can participate

3. Treatment
Testing the study drug, AZD5305

4. Follow-up
Monitoring your health and well-being after you stop the study treatment

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HRRm biomarker testing

Before you can join the study, some blood and tumour samples will be collected to look at some features called HRRm biomarkers. This is to help us understand if the study treatment is likely to work better for some people than others.

If you have any questions about the HRRm biomarker tests, you can talk to your study team for more information.

Main screening

After you have signed the main study ICF, you will be asked to have some tests and assessments to make sure the study is right for you. This is called the **screening** process, and it can take up to 4 weeks.

During screening, you will be asked to attend 1 clinic visit (or more if needed) to have some tests and assessments, including:

- Physical exams
- Heart tests*
- Checks of your vital signs (blood pressure, heart rate, body temperature)
- Blood and urine samples
- Scans of your body† and bones

*These may include an electrocardiogram (ECG) to check your heart's rhythm and electrical activity, and an echocardiogram (ECHO) or multigated acquisition scan (MUGA) to look at how well blood is flowing in and around your heart.

†Body scans may include computed tomography (CT), magnetic resonance imaging (MRI) and positron emission tomography (PET) scans.

You will be asked for a **sample** of your tumor at the start of the study. You may also be asked to provide another sample **if** your cancer gets any worse later in the study (*optional*).

If the study is not right for you, your study doctor will explain the reasons why. They will also talk to you about other possible treatments.

Treatment

In EvoPAR-Prostate01, you will start or continue to have treatment with **androgen-deprivation therapy (ADT)**. This is part of standard-of-care* treatment for your type of prostate cancer.

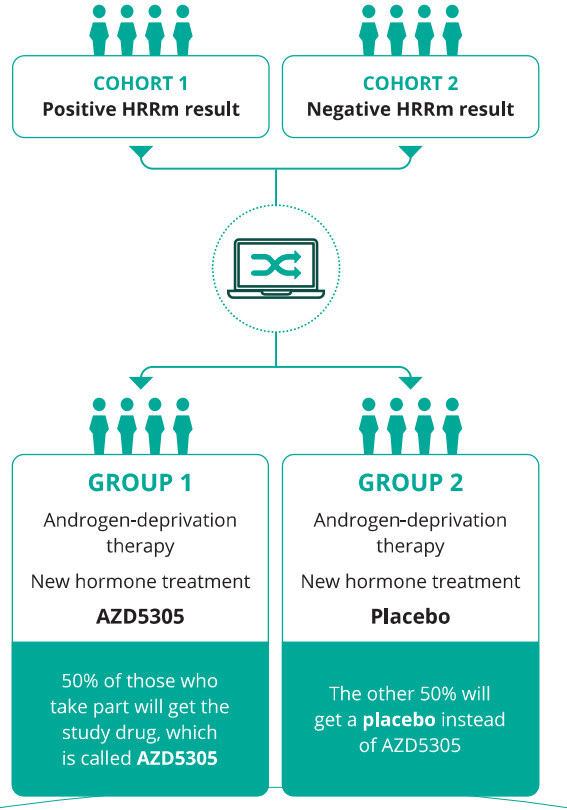
Everybody in the study will also start to have a hormone treatment (called a new hormonal agent, or NHA) they have not had before. This will be chosen by your study doctor. The choice will be based on which hormone treatment they think is best for you.

Based on the result of your HRRm biomarker test, you will be allocated to 1 of 2 cohorts: one for participants with positive biomarker test results and the other for participants with negative biomarker test results. Participants with unknown test results are not eligible to join the main study.

After screening, if you meet the criteria to join the study, a computer will decide at random which treatment you will receive.

*Standard-of-care treatment is a term for the level of care you would receive from any healthcare provider, based on your condition. For your type of prostate cancer, standard-of-care treatment is ADT with a new hormone treatment.

This is called '**randomization**'.



You and your study doctor won't know which treatment you are being given. This is sometimes called a **double-blind** study.

However, if there is an emergency and your doctor needs to know which treatment group you are in, the study team can find this out quickly.

What is placebo?

Placebo is used to help researchers find out if a new medicine is working. It looks exactly like the new treatment being studied but does not contain any active medicine.

Even if you don't receive AZD5305, you will still have the same level of treatment and care for your cancer.

During the treatment period, you will be asked to:

- Come to the study site to receive treatment and have tests and assessments to monitor your health, similar to the ones you have during screening
- Record how you are feeling and any symptoms you may be experiencing using an electronic device

It may be possible to do some of these things at your home or at your local clinic rather than at the study site. You may hear this being called a '**decentralized** study'.[‡]

Follow-up

After you stop taking AZD5305 and your hormone treatment, you will enter a part of the study called **follow-up**.

Follow-up is a very important part of the study. It allows your study doctor to monitor your well-being and collect more information about the study treatment.

If you decide to join the study, your study doctor will provide more details of your follow-up schedule.

[‡]Please know that this may not be the case in all countries taking part, because of different laws. The study team will be able to explain your options to you.

Frequently asked questions

What do I do if I have any side effects?

As with all medicines, the treatments in this study may have some side effects. If you do join the study:

- Your study doctor will discuss these with you in more detail
- The study team will monitor your health and well-being to prevent and manage any side effects

Can I change my mind?

YES — taking part in a clinical study is always your decision. You can stop taking part at any time, for any reason, and it will not affect the care you receive.

What if I need more support or information?

If you would like more information about EvoPAR-Prostate01, please speak to your doctor or contact the study team:

Study coordinator

(for example, a nurse appointed to the study)

NAME:

PHONE:

EMAIL:

ADDRESS:

The findings from this study may help people diagnosed with prostate cancer in the future.

If you are interested in taking part in the EvoPAR-Prostate01 study, please speak with your doctor for more information.