

What is a research study?



Before a new cancer treatment is approved for patients, it must go through testing to make sure it is both safe and effective. The process of testing a treatment in people is called clinical research. Clinical research is done very carefully, with strict oversight and adherence to ethical guidelines. The well-being of study participants is the number one priority.

Why is this study being done?



This study is being done to learn more about an investigational study medicine for prostate cancer. The study is for men whose prostate cancer has spread to other parts of the body (metastatic castration-resistant prostate cancer) and who have already been treated with chemotherapy.

Study-related treatment, imaging scans and doctor visits will be provided at no cost to you. The study clinic may provide additional help, such as paying you back for travel expenses.

Thank you for your interest in this study.

We are inviting men with advanced prostate cancer to consider joining our research study.

Allowing our research team to be part of your treatment journey could bring us one step closer to finding better treatment options for people with prostate cancer. We are here to answer any questions that you and your loved ones have.

With much appreciation,
The XALute Study Team

Your study doctor:

Phone: _____

Your study coordinator:

Phone: _____

Email: _____



Scan the code to visit
www.xalutestudy.com
for more information.



A research study for men with advanced prostate cancer

STUDY
OVERVIEW



Who can join the study?

You may be able to join the study if you:

- Have prostate cancer that has spread and no longer responds to hormone therapy.
- Have been treated with chemotherapy.

There are other requirements. The study doctor will talk with you and check to see if this study is right for you.

What is the investigational study medicine?

The investigational study medicine is in a different class of drugs than standard treatments. It is designed to help the immune system target and attack prostate cancer.

You'll get either the investigational study medicine or a current standard treatment chosen by your doctor. Standard treatment options include chemotherapy (cabazitaxel) or an androgen receptor pathway inhibitor (abiraterone or enzalutamide).



You have a two in three chance of receiving the investigational study medicine.



You have a one in three chance of receiving a standard treatment.

What happens during the study?

Your participation in the study may last up to 56 months. This includes time for the initial evaluation, study treatment and about 36 months of follow-up. During the study, you'll visit the study doctor regularly and have scheduled imaging scans.



PHYSICAL EXAM



HEART TESTS



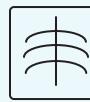
BLOOD TESTS



QUESTIONNAIRES



CT/MRI SCAN*



BONE SCAN*

*Every 8 weeks for 48 weeks, then every 12 weeks

CT = computed tomography;
MRI = magnetic resonance imaging.

How long you are treated will depend on how well your cancer responds and how well your body handles any side-effects.

What should I do next?

If you are interested in learning more and possibly joining the study:



Speak to the study staff. We will explain the study and answer your questions. We will also give you written materials to read at your own pace.



Talk to the people you trust to help you understand and make medical decisions. We welcome them to be part of the process and ask questions.



Read and sign the Informed Consent Form. Being in a study is 100% voluntary and you can leave at any time for any reason.

