A prostate cancer clinical trial

Chemotherapy and hormone treatment compared to hormone treatment alone in people with metastatic prostate cancer

PR.26 | NCT06592924

What is the purpose of this study?

The purpose of this study is to compare the effects on you and your prostate cancer of a new drug compared to other drugs which are the current standard treatment to treat this disease.

Why is this study important?

The drug being studied is a type of chemotherapy drug that has been used for the treatment of prostate cancer, but it is not clear if it can offer better results than standard treatment for patients with metastatic castration sensitive prostate cancer with less than optimal **prostate-specific antigen (PSA)** response.

Who can participate in this study?

This trial is for:

- Males (assigned male at birth) ≥18 years of age
- Patients with confirmed adenocarcinoma of prostate
- Patients with prostate cancer that has spread
- Patients with elevated PSA levels
- Patients who have received treatment with Androgen Pathway Receptor Inhibitor (ARPI) for at least 4 months and Androgen Deprivation Therapy (ADT) for at least 6 months

This trial is not for:

- Patients with evidence that their disease has progressed on ARPI and ADT
- Patients who have not recovered from any recent therapy or intervention such as surgery
- Patients with known active and/or untreated Hepatitis B or Hepatitis C
- Patients on another treatment for cancer other than hormone therapy (ADT and ARPI)
- Patients who previously took a drug similar to the one being studied here

What are the risks?

If you choose to take part in this study, there is a risk that the study drug may not be as good as the standard treatment at shrinking or stabilizing your cancer. There is also a risk that you could have side effects from the study drug. Some of the most common side effects that the study doctors know about are:

- Nausea and vomiting
- Diarrhea
- Decrease in the number of white blood cells (leukopenia) including certain kinds of white blood cells (neutrophils and lymphocytes) in your blood. When your blood counts are low, you are at risk of serious, life-threatening infections. Your doctor will explain to you what to do if this happens.
- Hair loss which may rarely be permanent
- Tiredness, weakness

You will find details of all side effects in the consent document.

What can I expect?

If you choose to take part in this study, you will be randomly placed in one of two groups and you will receive either the new drug in addition to the drugs commonly used to treat this disease or the drugs commonly used to treat this disease alone.

How can I find out more or join the study?

Talk to your cancer doctor if you are considering joining this study. You can share summaries like this with them and ask if they think joining the trial may be a good option for you.

Before you join this study, you will be asked to review an *Informed Consent* document which will tell you more about why the research is being done and your role as a participant. You will have an opportunity to discuss anything that is not clear and ask any questions you have.

Joining this study is entirely up to you and you can decide to leave at any time without giving a reason. Your decision to join or leave the trial will not affect your standard medical care.

The **PR.26** study is currently enrolling patients at cancer centres in Canada and the USA. For a full list of participating cancer centres and more information about the study, please visit www.clinicaltrials.gov and search using NCT06592924.