

Metastatic castration-resistant prostate cancer

A study to test inavolisib treatment in people with castration-resistant prostate cancer that has spread to other parts of the body

A Study to Test Inavolisib Treatment in Participants With Metastatic Castration-Resistant Prostate Cancer

Trial Status
Recruiting

Trial Runs In
10 Countries

Trial Identifier
NCT07287150 2025-521327-67-00
CO45813

The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

Official Title:

A Phase II, Randomized, Multicenter, Open-Label Study Evaluating the Efficacy and Safety of the Combination of Inavolisib Plus Enzalutamide Versus Physician's Choice of ARPI or Docetaxel in Patients With Metastatic Castration-Resistant Prostate Cancer

Trial Summary:

This study will evaluate the efficacy and safety of the combination of inavolisib plus enzalutamide compared with physician's choice of alternative androgen receptor pathway inhibitor (ARPI) or docetaxel in biomarker-selected participants with metastatic castrate-resistant prostate cancer (mCRPC) who have received one prior second-generation ARPI.

Hoffmann-La Roche
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Phase 2
Phase

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Trial Identifiers

Eligibility Criteria:

Gender
Male

Age
#18 Years

Healthy Volunteers
No

1. Why is this study needed?

Metastatic castrate-resistant prostate cancer (mCRPC) is an advanced stage of prostate cancer. It happens when the cancer stops responding to treatments that lower

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testosterone levels (castration-resistant) and has spread to other parts of the body (metastatic). Testosterone is a male hormone that helps prostate cancer grow, so many treatments aim to reduce its levels. Researchers are looking into new treatment options to help manage the disease better.

This study is testing a medicine called inavolisib. It is being developed to treat mCRPC.

Inavolisib is an experimental medicine. This means health authorities (like the U.S. Food and Drug Administration and European Medicines Agency) have not approved inavolisib (in combination with enzalutamide) for the treatment of mCRPC.

This study aims to compare the effects of inavolisib plus enzalutamide versus standard treatments which include hormone treatments (enzalutamide or abiraterone) or chemotherapy (docetaxel), in people with mCRPC.

2. Who can take part in the study?

Men who are 18 years of age or older can take part in the study if they have mCRPC that is getting worse and low testosterone levels (less than 50 ng/dl). They should have certain changes (called mutations) in their cancer cells. To check for these specific cancer markers, they need to be willing to provide a previously collected tumor sample. If a previous sample is not available, a new small tissue sample may be taken by a procedure called a biopsy.

People may not be able to take part in this study if they have cancer that has spread to the liver. They will also be excluded if they have diabetes or pre-diabetes, have previously received certain cancer treatments or if they are not able to swallow pills.

There may be additional criteria that people must meet, which can be determined after speaking with a study doctor.

3. How does this study work?

People will be screened to check if they are able to participate in the study. First, there will be a prescreening period of up to 3 months before the start of treatment to check for the presence of the specific cancer mutation. Then, if they have the biomarkers needed to participate in the study (biomarker positive), a screening period will take place from 28 days before the start of treatment to check if they meet the other study requirements. The treatment will be given in cycles, each lasting 3 weeks.

Everyone who joins this study will be split up into 2 groups randomly (like flipping a coin). Participants will have an equal chance of being placed in one of the following treatment groups:

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- Group 1 will receive inavolisib plus enzalutamide every day, both given as pills
- Group 2 will receive either enzalutamide or abiraterone, as a pill every day, or receive docetaxel, as a drip into the vein (intravenous infusion) every three weeks

Group 1 participants and Group 2 participants who are on abiraterone or enzalutamide will keep taking their treatments until the cancer gets worse. Docetaxel will be given for a maximum of 10 cycles only.

After an early review of study results, participants who do not have a certain cancer mutation (biomarkernegative) may also be included in a separate group. In this particular group, one set of participants will receive inavolisib plus enzalutamide every day, both given as pills, while the other set will receive only enzalutamide as a daily pill.

This is an open-label study. This means everyone involved, including the participant and the study doctor, will know the study treatment the participant has been given.

During this study, the study doctor will see participants at the minimum every week for the first 3 cycles. After that, they will be seen once every 3 weeks for the rest of the study. They will receive the treatment until their disease gets worse or they experience unwanted effects that require stopping. Participants will have 1 safety follow-up visit after 1 month of completing the study treatment. In addition to the standard follow-up visit at 1 month for all participants, those who develop a high level of sugar in the blood after receiving inavolisib treatment will have monthly follow-up visits for up to 3 months. During these visits, the study doctor will check on the level of glucose and participant's well being. The total time of participation in the study will be about 3 years. Participants have the right to stop study treatment and leave the study at any time, if they wish to do so.

4. What are the main results measured in this study?

The main results measured in the study to assess if the medicine has worked are how long participants live without their cancer getting worse compared to those who did not get the medicine. Regular scans will be conducted to assess changes in the cancer. Other key results measured in the study include:

- How many participants have a reduction of their cancer after treatment
- Number of participants with more than 50% and 90% decrease in prostate specific antigen (a protein produced by the prostate and present in the blood, which can be linked to cancer)
- How much time there is between the participant's cancer first responding to treatment and the cancer getting worse
- How long participants live
- Number and seriousness of unwanted effects

5. Are there any risks or benefits in taking part in this study?

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Taking part in the study may or may not make participants feel better. But the information collected in the study can help other people with similar health conditions in the future.

It may not be fully known at the time of the study how safe and how well the study treatment works. The study involves some risks to the participant. But these risks are generally not greater than those related to routine medical care or the natural progression of the health condition. People interested in taking part will be informed about the risks and benefits, as well as any additional procedures or tests they may need to undergo. All details of the study will be described in an informed consent document. This includes information about possible effects and other options of treatment.

Risks associated with the study medicines

Participants may have unwanted effects of the medicines used in this study. These unwanted effects can be mild to severe, even life-threatening, and vary from person to person. During this study, participants will have regular check-ups to see if there are any unwanted effects.

Participants will be told about the known and possible unwanted effects of inavolisib, enzalutamide, abiraterone and docetaxel, based on human and laboratory studies or knowledge of similar medicines. Known unwanted effects include a high level of sugar in the blood, feeling tired or weak, wanting to throw up, throwing up, and swelling or ulcers in the mouth or lips. Participants will be told about any known side effects of swallowing tablets and intravenous infusions.

Known unwanted effects of infusion include allergic reactions such as flushing, skin reactions, itching, chest tightness, difficulty in breathing, fever or chills, back pain and low blood pressure.

The study medicines may be harmful to an unborn baby. Women and men must take precautions to avoid exposing an unborn baby to the study treatment.

Inclusion Criteria:

- Histologically or cytologically confirmed adenocarcinoma of the prostate without small-cell or neuroendocrine features
- Progressive metastatic CRPC, defined as any of the following: PSA progression, defined by a minimum of two rising PSA values from three consecutive assessments with an interval of at least 7 days between assessments and with a minimal starting value of PSA ≥ 1 ng/mL; The most recent qualifying PSA value must be determined within 14 days of enrollment; Soft tissue disease progression, defined by Response Evaluation Criteria in Solid Tumors, Version 1.1 (RECIST v1.1); Bone disease progression, defined by PCWG3 criteria, with two or more new metastatic bone lesions on a whole-body radionuclide bone scan
- Treatment with at least one, but no more than one, prior second-generation ARPi (abiraterone, apalutamide, enzalutamide, darolutamide) for hormone-sensitive prostate cancer (HSPC) or CRPC
- Availability of a tumor tissue specimen that is suitable (e.g., adequate quality and quantity) for use in determining biomarker status

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- Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1
- Fasting glucose <100 mg/dL and HbA1c < 5.7%

Exclusion Criteria:

- Presence of liver metastasis
- Prior treatment with any phosphatidylinositol-3-kinase (PI3K), protein kinase B (AKT), or mammalian target of rapamycin (mTOR) inhibitor, or with any agent with a mechanism of action of inhibiting the PI3K/AKT/mTOR pathway
- Type 1 or Type 2 diabetes mellitus
- Prior treatment for mCRPC with cytotoxic chemotherapy or novel hormonal treatments (e.g., androgen receptor degraders, CYP11 inhibitors), with the following treatments permitted: Prior docetaxel in mHSPC, providing no evidence of disease progression occurred during treatment or within 6 months of treatment completion; Prior docetaxel in the adjuvant or neoadjuvant setting providing no evidence of disease progression occurred during treatment or within 12 months of treatment completion; Prior treatment with sipuleucel-T, with the last dose administered >28 days prior to start of treatment; Prior PARPi therapy, as per local prescribing information, with the last dose administered >14 days prior to start of treatment; One prior RLT or radiotherapeutic agent (e.g., PSMA-targeted RLT, Radium 223) with the last dose administered >8 weeks prior to start of treatment
- Other concurrent anti-cancer therapy except for androgen deprivation therapy
- Treatment with strong CYP2C8 inhibitors, strong or moderate CYP2C8 inducers, or strong CYP3A4 inducers within 1 week or 5 drug-elimination half-lives, whichever is longer, prior to initiation of study treatment
- Transfusion of any blood product for the sole purpose of making a potential participant eligible for study inclusion or within 28 days of enrollment