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# Learn about a clinical trial for Metastatic Castration Resistant Prostate Cancer (mCRPC)

In this brochure, you will learn about **metastatic castration resistant prostate cancer (mCRPC)** and a clinical trial for this disease. In this trial, researchers are trying to find out if an investigational drug, MK-5684, alone or in combination with other drugs, is safe and if it may help slow down or stop this disease from spreading to other areas of the body.

You can use this brochure to talk with your doctor about this trial.



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## What is Metastatic Castration Resistant Prostate Cancer (mCRPC)?

Metastatic prostate cancer is cancer that has spread from your prostate to other parts of your body. Castration-resistant means that the cancer no longer responds to a medical or surgical treatment that lowers testosterone. It's called mCRPC for short.

### Here is how mCRPC develops:

1. Male hormones (such as testosterone) help prostate cancer grow.
2. Men usually first get treatment to lower their levels of male hormones to shrink the cancer in the prostate and other areas where it has spread. This is called androgen deprivation therapy (ADT).
3. However, prostate cancer can eventually grow and may need more treatments to help stop it again. This is when the prostate cancer is called mCRPC.



**Deciding to join a clinical trial is something only you, those close to you, and your care team can decide together. If there is anything you do not understand, ask the trial doctor.**

# What are my treatment options?

If you have mCRPC, your care team will talk about your treatment options with you and those close to you. Your options will depend on a few things:

## Your options will depend on a few things:

- Your overall health
- The stage of your cancer, which tells you if it has spread and how far
- The type of prostate cancer you have. Doctors can tell what type you have by looking at a sample of your tumor under a microscope.
- Treatments you have already received for prostate cancer
- Chance of the cancer coming back
- Side effects you might have from the treatment
- What chance the treatment has of slowing down or stopping the cancer
- How long the treatment might help extend your life
- How much the treatment might help improve your symptoms

## Your care team may offer you 1 or more of these treatments:

- **Hormone therapy** - treatment that stops hormones from helping cancer grow
- **Radiation therapy** - treatment that uses beams of intense energy (like X-rays) to shrink or get rid of tumors. This would only be used to treat symptoms related to tumor growth.
- **Immunotherapy** - medicines that help your immune system fight the cancer
- **Chemotherapy** - medicine to kill cancer cells or stop them from growing
- **Targeted therapy** - treatment that works on specific cells to stop them from growing
- **Palliative care** - also called comfort care. This is special care to help ease pain and symptoms with a focus on the person's quality of life. This does not directly treat mCRPC, but it helps keep you as comfortable as possible.
- **Clinical trials**, such as this one

**Talk to your doctor to find out which treatment is right for you.**



# What is a clinical trial?

Clinical trials are research studies that help doctors find out if study drugs (alone or with other treatments) are safe and if they can help prevent, find, or treat diseases or conditions. Clinical trials are carefully controlled research studies that are done to get a closer look at investigational treatments and procedures.

## All about this clinical trial

### What is the goal of this clinical trial?

The goal of this trial is to learn if the investigational trial drug, MK-5684, alone or in combination with other drugs, is safe and if it may help slow down or stop this disease from spreading to other areas of the body.

This trial will test MK-5684 when given alone or in combination with 1 of 3 other drugs that are used to treat different types of mCRPC: olaparib, docetaxel, or cabazitaxel. The combination of MK-5684 with any one of these drugs is experimental. This trial is also being done to determine recommended doses for MK-5684 in combination with olaparib, docetaxel, or cabazitaxel.



### What is the treatment being studied?

This clinical trial is studying the investigational drug called MK-5684, to see if it may slow or stop the growth of prostate cancer by stopping the body from making steroid hormones.

#### **Steroid hormones are chemical messengers that help your body control processes, such as:**

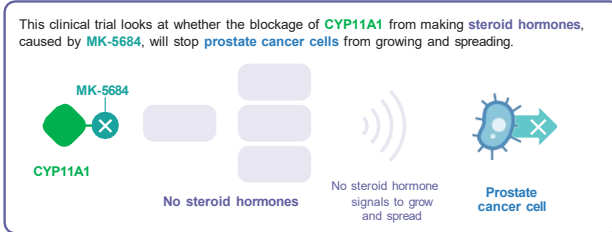
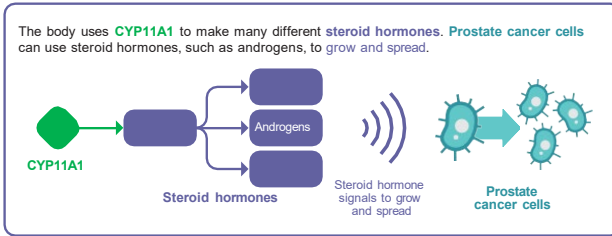
- Your metabolism – the process that turns your food and drinks into energy in your body
- Your immune system – the process that protects your body from infection
- Blood pressure
- Development of sexual characteristics such as puberty

Androgens are a type of steroid hormone that certain types of prostate cancer cells can use to grow and spread. Many proteins in the body help make androgens. One of these proteins is called CYP11A1.

MK-5684 may help slow or stop prostate cancer by blocking CYP11A1 from making androgens and other steroid hormones.

Since MK-5684 blocks this protein and stops the body from making all steroid hormones, participants who are taking the investigational drug, MK-5684, must take the investigational drug with hormone replacement therapy (HRT).

# Another way to think about MK-5684



## What is hormone replacement therapy (HRT)?

Your body needs steroid hormones to function. Since the investigational drug, MK-5684, prevents the body from making any steroidal hormones, participants in this trial will need to also take **hormone replacement therapy (HRT)** every day. HRT drugs act as a replacement for some of the steroid hormones.

People who take MK-5684 in this trial must also take 2 HRT drugs called fludrocortisone and dexamethasone.

It is very important to take HRT drugs with MK-5684. Taking MK-5684 without any HRT drugs can cause **adrenal crisis**, a serious medical emergency that can result in death.

## What is adrenal crisis?

Adrenal crisis is when your body has a very low level of the steroid hormones that are usually made by your adrenal glands. Your adrenal glands make these hormones and are located at the top of your kidneys.

### Signs and symptoms of adrenal crisis include:

- Severe tiredness, weakness, lack of energy
- Low blood pressure, feeling lightheaded or dizziness when standing up
- Abdominal pain, tenderness
- Nausea (feeling sick to your stomach) or vomiting (throwing up)
- Fever
- Confusion or increased sleepiness
- Back and/or leg cramps or spasms
- Generalized darkening of the skin
- Rapid breathing
- Unusual and excessive sweating



Adrenal crisis is a serious medical emergency. If you have any of these symptoms while in this trial, seek medical care right away. It can be treated with a steroid drug called hydrocortisone.

While you are taking MK-5684 in this trial, you may need to take hydrocortisone if you have symptoms of adrenal crisis. The trial doctor will discuss this with you.

The trial doctor and staff will give you an emergency kit with hydrocortisone to use in case of adrenal crisis. They will teach you how to recognize the symptoms of adrenal crisis and what to do if you have them. They will also give you:

- A steroid emergency card that gives information about your participation in the trial and why you need to take steroid drugs. You should show this card to your healthcare professional whenever you get health care outside of the trial.
- A card that lists symptoms of adrenal insufficiency (not having enough steroid hormones) and adrenal crisis. It also has instructions to follow if you have these symptoms.
- Instructions for how to use the emergency kit

## Who can join this trial?

There are eligibility criteria that will determine if you will qualify for participation. For example, you must be at least 18 years old and have:

- mCRPC that has become worse within 6 months before starting the trial and:
  - After being treated with drugs or surgery to block your testes from making hormones
- AND
- After treatment with other drugs for prostate cancer

Your trial staff will do tests to see if you are able to join this trial.

### You and your trial doctor will discuss:

- All the requirements to join this trial
- Possible benefits, risks, and side effects of being in this trial

Deciding to join a clinical trial is something only you, those close to you, and your care team can decide together. If there is anything you do not understand, ask the trial doctor.

## If I join, how long will I be in the trial?

How long you will be in the trial depends on:

- Your health
- What type of cancer you have
- How well you tolerate the study treatments



## What will happen during trial visits?

You will visit the trial site on a regular schedule so that the trial doctors can see how the trial drug is working for you. During your trial visits, you may get:

- Your trial treatments
- Blood and urine tests
- Physical exams
- Imaging scans such as CT scans or MRIs (scans that help the doctor see the cancer inside your body)

You can ask your trial doctor any questions you have about what happens during trial visits and how often they will happen.

If you are able to join the trial, your trial doctor will need to stay in contact with you even after your trial visits are over. This is very important because this clinical trial is studying how well the study treatment works over time.

## What treatments will I get?

The treatments you will get will depend on which group you are placed in. This trial has 4 groups:

<b>Group 1</b>	MK-5684 only
<b>Group 2</b>	MK-5684 in combination with Olaparib
<b>Group 3</b>	MK-5684 in combination with Docetaxel
<b>Group 4</b>	MK-5684 in combination with Cabazitaxel

The first participants in this trial will be placed into Group 2, Group 3, or Group 4 to find an acceptable dose for olaparib, docetaxel, or cabazitaxel in combination with MK-5684.

Once an acceptable dose is determined for at least one of the combination treatments (olaparib, docetaxel, or cabazitaxel), Group 1 (MK-5684 only) will be open for enrollment.

A computer will place you in one of the groups that are open for enrollment when you join the trial. You have an equal chance of being put into any of the groups that you are eligible to be in (if you have been treated with olaparib, docetaxel, or cabazitaxel before joining the trial, you will not receive that drug as the combination treatment in the trial).

The trial doctor will tell you which groups are open for enrollment when you join.

You, your trial doctor, and the trial staff will know what trial drugs you are getting.

Deciding to join a clinical trial is something only you, those close to you, and your care team can decide together. If there is anything you do not understand, ask the trial doctor.



**Thank you for learning about mCRPC and this clinical trial.**

You can use this brochure to talk with your doctor about this trial.

## **Your questions and notes:**

You can use this space to write down notes or questions about this trial.

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## **To learn more**

To learn more about this trial, you can:

- Talk to your doctor
- Contact Merck by
  - o Visiting [www.merckoncologyclinicaltrials.com](http://www.merckoncologyclinicaltrials.com)
  - o Scanning this QR code:

