



Omaha-004

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, (also called opevesostat), is safe and if it may help slow down or stop this disease from spreading to other areas of the body. Researchers will compare the investigational drug with standard treatments for mCRPC.

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 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 (also called opevesostat), when taken with 2 hormone replacement drugs, is safe and may help to slow down or stop the growth of mCRPC.

This trial will compare MK-5684 to abiraterone acetate or enzalutamide, which are treatments that doctors currently use to treat mCRPC.

What is the study treatment being researched?

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:

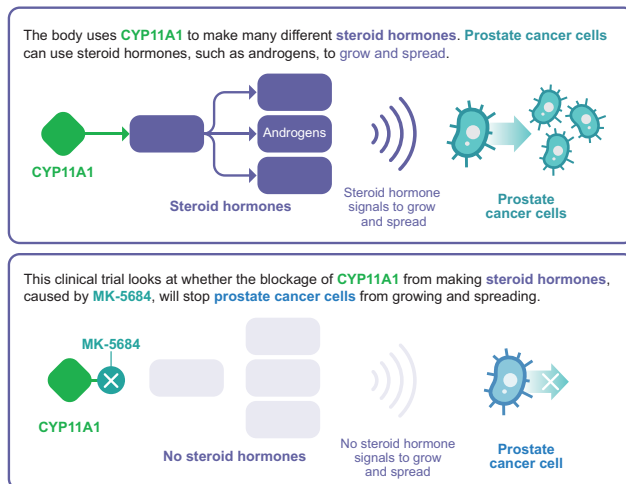
- Your metabolism – the process that turns your food and drinks into energy in your body
- Your immune system – the process that protects your body from infection
- Blood pressure
- Development of sexual characteristics such as puberty

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.

If you are assigned to take 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:

- Advanced mCRPC (stage 4 metastatic prostate cancer)
 - mCRPC that became 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.

There may be reasons why you cannot be in this trial. To be in this trial, you need to have your blood sample tested to check whether your genes have a certain androgen receptor mutation (changes in your genes related to your hormones). This is called the AR LBD mutation. The mutation can be present or absent.

Because the trial may need a certain number of participants both with and without the mutation, the number of participants may be limited. That may mean you may not be able to join the 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

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, bone 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 study treatments will I get?

The treatments you will get will depend on which group you are placed in. This trial has 2 groups:

- **Group 1** will get the investigational drug, MK-5684, and 2 HRT drugs, fludrocortisone and dexamethasone.
 - People will take MK-5684 twice a day
 - People will take fludrocortisone and dexamethasone once a day
- **Group 2** will get either abiraterone acetate or enzalutamide. The trial doctor or staff can tell you which drug you will get if you are put in Group 2. Abiraterone acetate can cause the adrenal glands to make less of a hormone called cortisol. People assigned to take abiraterone acetate will also get a steroid drug called prednisone or prednisolone to help levels.
 - People will take abiraterone acetate or enzalutamide once a day
 - People will take prednisone or prednisolone twice a day

A computer will decide which group you are put in. You have an equal chance of getting put in each group. You, your trial doctor, and the trial staff will know what treatments you are getting.

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.

To learn more

To learn more about this trial, you can:

- Talk to your doctor
- Visit www.merckclinicaltrials.com/oncology
- Scan this QR code:



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