



MK 3475-U04

A Clinical Trial for Bladder Cancer

In this brochure, you will learn about Bladder Cancer and a clinical trial for this disease. This clinical trial is trying to find out if investigational study drugs or investigational combinations of study drugs can help stop or slow down locally advanced or metastatic Bladder Cancer.



What is Bladder Cancer?

Bladder cancer (also called urothelial carcinoma) is a type of cancer found in the inner layer of cells that line the urinary tract, called the urothelium. The urinary tract is several organs that work together to remove urine from our bodies. The urinary tract includes the kidneys, ureter, bladder, and urethra. This type of cancer is often called bladder cancer because it most often occurs in the bladder, but it can happen in other parts of the urinary tract too.

What are some common types of bladder cancer?

Bladder cancer can progress through several stages. In this trial, we will be enrolling bladder cancer patients whose tumors are either locally advanced/unresectable or metastatic.

Locally advanced/unresectable disease means that the cancer has grown outside of the bladder and can no longer be completely removed by surgery.

Metastatic disease means that the cancer has spread from the bladder to other distant parts of the body. For example, bladder cancer that has spread to the lungs, liver, or bones would be metastatic.

What is a clinical trial?

A clinical trial (also known as a clinical study) is a research study that helps doctors find out if investigational study drugs (alone or with other treatments) are safe and if they can help prevent or treat diseases or conditions.

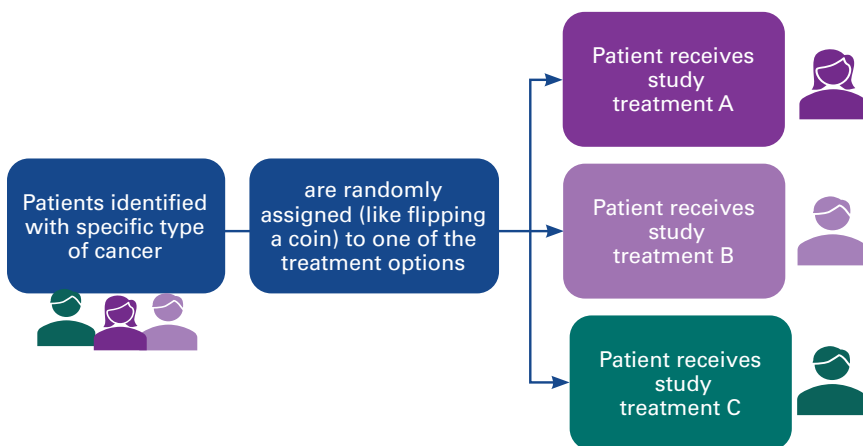


What is an Umbrella Clinical Trial?

Umbrella trials are clinical trials that look at many investigational study drugs or investigational combinations of study drugs in the treatment of a specific type of cancer.

Throughout the course of the study, new treatment options may be added or removed from the study as we learn more about what works and doesn't work in the treatment of bladder cancer.

What does an Umbrella Clinical Trial Design look like?



Just like other clinical trials, patients who have the type of cancer the study is investigating may be eligible to enroll. Patients will undergo screening procedures to determine if they meet all the criteria to enroll in the umbrella trial. If eligible and enrolled, patients will be randomly assigned (like flipping a coin) to one of the treatment options of the umbrella trial.

Why is this study being done?

This study is looking to see whether certain investigational medications may be effective at stopping or slowing down the spread of locally advanced or metastatic urothelial carcinoma. This umbrella trial will look at multiple investigational drugs or combinations of investigational drugs in the treatment of locally advanced or metastatic urothelial cancer.

Who can join this trial?

There are criteria that you must meet to join the trial, such as being diagnosed with locally advanced or metastatic bladder cancer.

If you decide to join, you will be asked to undergo screening procedures to determine if you meet all criteria to enroll in the trial.

You and your trial doctor will discuss the other criteria to decide if this trial is a good option for you, as well as the possible benefits and risks of joining the trial.

Your treatment options

If you have bladder cancer, your cancer care team will discuss your treatment options with you and those close to you. Your options will depend on several things:

- The stage of your cancer
- Your overall health
- Types of standard treatments that may be available for you
- Side effects you might have from the study treatment
- What chance the treatment has of reducing or removing this disease

Your care team may offer you one or more of these options:

Targeted therapy – uses treatments to block a specific or unique feature that helps the cancer grow and spread

Immunotherapy – treatment that helps the patient's immune system fight the cancer

Chemotherapy – use of medicine (drugs) to kill cancer cells

Radiation therapy – use of high energy radiation to kill cancer cells and shrink tumors. This would only be used to treat symptoms related to tumor growth in specific areas of the body.

Palliative care – your care team will try to make you comfortable but not treat the disease

Clinical Trials – such as this one

If I join, what will happen during study visits?

You will visit the study site on a regular schedule so that your doctor can see how the study drugs are working for you. During your study visits, you might get:

- Blood tests
- Physical Exams
- Research study drugs
- Imaging scans such as CT scans or MRIs

What are the risks and benefits of joining a clinical trial?

There are risks and benefits to joining any clinical trial. You may have side effects from the treatment. During a clinical trial, researchers may learn more about how well a study treatment works.

If you decide to join a clinical trial, the trial doctor will explain what side effects could happen. Researchers do not always know all the possible side effects of a study treatment.

What is Long-Term Follow-Up?

After the clinical trial has ended, your trial team will contact you to ask about your health. This is called **long-term follow-up**. This type of follow up helps doctors learn if the clinical trial treatment helps people to live longer or to have a better quality of life.



Ask your doctor any questions you may have about your treatment options and how to find clinical trials that may be available to you. Be sure to write down any questions you have for your doctor.



Write any questions or notes



