INTerpath

ONCOLOGY CLINICAL TRIALS

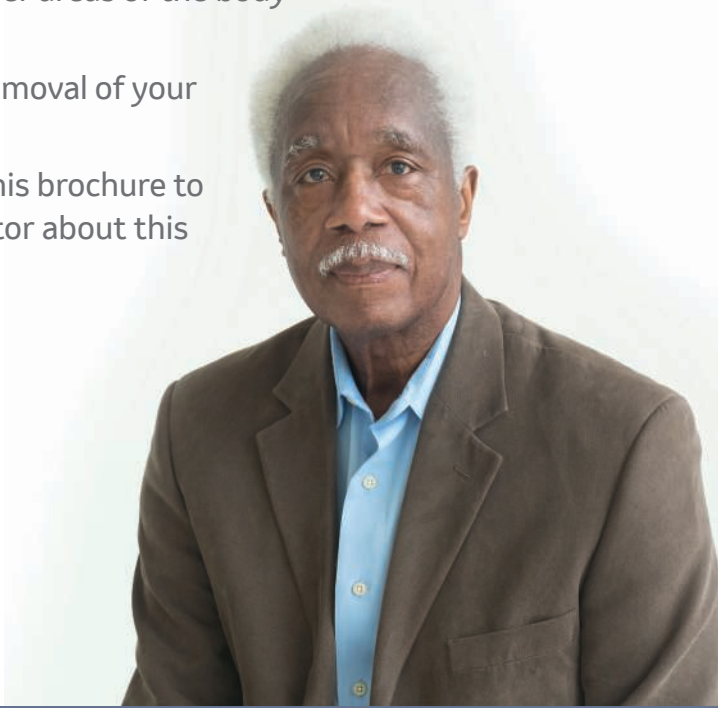
INTerpath 011

A clinical trial for **people with bladder cancer**

In this brochure, you will learn about **high-risk non-muscle invasive bladder cancer (HR NMIBC)** and a clinical trial for this disease. In this trial, researchers are trying to find out if an investigational trial drug

- is safe and
- may help slow down or stop your bladder cancer from spreading to other areas of the body
  or
- may delay the removal of your bladder

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



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What is bladder cancer?

Bladder cancer is a type of cancer in the inner layers of cells that line the urinary tract. It's often called bladder cancer because it most often happens in the bladder, but it can happen in other parts of the urinary tract too.

The **urinary tract** is a set of organs that work together to remove urine (pee) from your body, which includes:

- **Kidneys** – organs that filter waste and extra water from blood to make urine
- **Ureter** – tube that carries urine from the kidney to the bladder
- **Bladder** – organ that stores urine
- **Urethra** – tube that empties urine from the bladder to leave the body

Non-muscle invasive bladder cancer (NMIBC) means the cancer has not spread to the muscle layer of the bladder lining. NMIBC has 3 risk categories, which describe how likely the cancer is to grow or come back. The 3 risk categories are:

- **Low-risk** – the cancer is less likely to grow or spread. It usually involves small, single tumors.
- **Intermediate-risk** – the cancer has a medium chance of growing or spreading. It might involve larger or multiple tumors, or tumors that have certain features making them more concerning than low-risk.
- **High-risk** – the cancer is more likely to grow or spread to deeper layers of the bladder or more likely to come back after treatment. It includes larger tumors, multiple tumors, or tumors that have features known to be more aggressive.

What are my treatment options?

If you have **high risk non-muscle invasive bladder cancer** (HR NMIBC), 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 and risk category of your cancer, which tells you if the cancer has spread and how far
- The 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:

- **Local therapies** – treatment directed at the site of the cancer to destroy it
    - **Targeted therapy** – treatment that works on specific cells to stop them from growing
    - **Immunotherapy** – medicines that help your immune system fight the cancer
    - **Chemotherapy** – medicine to kill cancer cells or stop them from growing
    - **Radiation therapy** – treatment that uses beams of intense energy (like X-rays) to shrink or get rid of tumors.
- **Radical cystectomy** – surgery to remove the bladder
- **Watchful waiting** – your care team might wait and watch the cancer before they use any treatment (also called active surveillance)
- **Clinical trials**, such as this one

Talk to your doctor about 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.

About this clinical trial

What is the goal of this clinical trial?

The goal of this trial is to learn if V940, an investigational trial drug, administered alone or in combination with **Bacillus Calmette-Guerin (BCG)** is safe and can help slow down or stop HR NMIBC from coming back or spreading to other areas of the body more effectively than BCG alone.

What treatment is being studied?

The investigational trial medicine is V940 (also known as mRNA-4157). V940 is given as an injection into your arm.

Researchers will compare the investigational drug, V940, in combination with BCG to BCG alone. Researchers will also evaluate V940 when given alone.

About V940

V940 is an investigational cancer therapy that has not been approved.

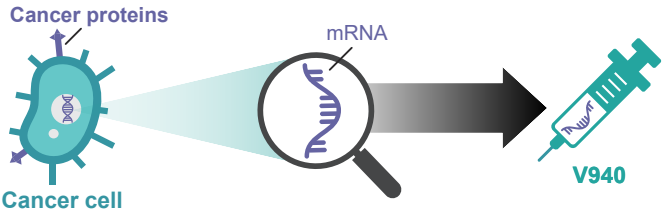
1. Every person's cancer has different mutations (changes) in their genes. V940 is made specifically for each person based on their gene mutations- in other words, it is individualized for each person.
2. Before a person gets V940, researchers find their cancer mutations. They then make mRNA to use in a dose of V940 made just for them (**mRNA** is genetic material that tells your body how to make proteins). The mRNA makes proteins that look like the person's specific cancer mutations.

3. When the person gets V940 as an injection into their muscles, the mRNA tells their body to make proteins that look like their cancer mutations.
4. These proteins may help the immune system recognize and attack cancer cells with these mutations.

Another way to think about V940

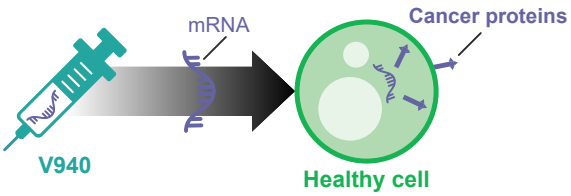
1

Researchers find gene mutations unique to a person's **cancer cells** that make **cancer proteins**. They then use these genes to make mRNA for **V940** that is unique to a person's cancer.



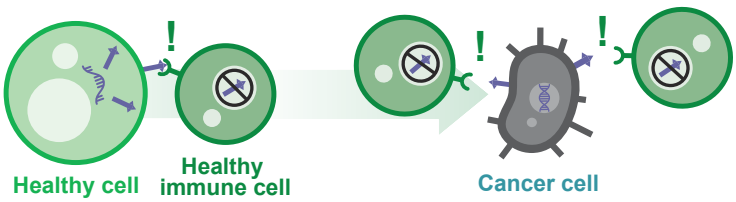
2

When **V940** gets in **healthy cells** in the body, the cells use the mRNA to make proteins like the **cancer proteins**.



3

The **cancer proteins** from the **healthy cells** may train **healthy immune cells** to find and attack the **cancer cells**.



About BCG

BCG is a type of immunotherapy, which may help the body's immune system attack cancer cells. BCG has been approved by some health authorities to treat HR NMIBC, but it may not be approved in your country. BCG is given directly into the bladder by a small tube called a catheter.

Who can join this trial?

There are eligibility criteria that will determine if you will qualify for participation.

For example, you must:

- Be 18 years of age of older
- Have a confirmed diagnosis of HR NMIBC
- Be able to provide tissue and blood samples

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?

Everyone who joins will be in the trial for about 5 years. Your time in the study will start when you sign the informed consent document. It will end with your last contact with the trial staff.

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(s) are working for you. During your trial visits, you may get:

- The trial drug(s)
- Blood and urine tests
- Physical exams and vital signs
- Scans and procedures such as:
    - Biopsy with the goal of removing your bladder cancer (called TURBT)
    - Urine cytology, a test to check for cancer cells in your urine
    - A test to check how you heart is beating (called an electrocardiogram or ECG)
    - Scans to see and take pictures of the inside of your bladder and urinary tract (called CTU/MRU)

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 get will depend on which group you are placed in. There are 3 groups:

Group 1 will get BCG and V940

Group 2 will get only BCG

A computer will decide which group you are put in. You have an equal chance of being put in group 1 and 2.

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.

For **Group 3**, you either refused to or cannot receive treatment inside your bladder and will get only the investigational drug, V940.

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

Thank you for learning about high-risk non-muscle invasive bladder cancer (HR NMIBC) 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
- Contact Merck by
  - Visiting www.merckoncologyclinicaltrials.com
  - Scanning this QR code:

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For more information, contact our research staff: