Clinical trial summary (S1937)

Adding the New Drug Eribulin to Gemcitabine Chemotherapy for Urothelial Bladder Cancer That Has Spread

What is the purpose of this clinical trial?

This study tests combining 2 chemotherapy drugs, eribulin and gemcitabine, to treat bladder cancer that has spread to other places in the body.

- **Eribulin** is a chemotherapy drug that is used to treat other types of cancer.
- **Gemcitabine** is a chemotherapy drug that doctors currently use to treat bladder cancer.

The Food and Drug Administration (FDA) has approved several different chemotherapy drugs for bladder cancer that has spread. This study will compare the combination of eribulin and gemcitabine to the current treatment options.

This trial is set up to find out:

- If chemotherapy using both eribulin and gemcitabine can help people with bladder cancer live longer than the current treatments
- If chemotherapy using both eribulin and gemcitabine can help control bladder cancer for a longer time than the current treatments

Why is this trial important?

Combining eribulin and gemcitabine has been tested in smaller research studies. There is evidence that the drugs work together to help control advanced bladder cancer, but doctors don't know if the combination is better than current treatments.

This trial is a chance to learn if using eribulin and gemcitabine together can improve chemotherapy options for people with bladder cancer. It may lead to better treatments for patients in the future.

Who can be in this trial?

This trial is for adults, age 18 or older, with urothelial bladder cancer that has spread to other places in the body.

This trial is for people who:

- Received the drug enfortumab vedotin (Padcev) in a previous treatment
- Received immunotherapy in a previous treatment (if your doctor determined that this type of therapy was not an option for you, you may still be able to join this trial)
- Have cancer that has grown or spread after previous treatment

This trial is not for people who:

- Have an active infection of HIV, hepatitis B, or hepatitis C
- Have poor liver or kidney function
- Are pregnant

Talk with your doctor to learn more about who can join this study.

What treatments will I get?

A computer will randomly assign you to one of 2 study groups.

Usual Treatment Group

You'll receive one of the usual chemotherapy drugs. The drug options are:

- **gemcitabine**
- **docetaxel** OR
- **paclitaxel**

You and your doctor choose which one is best for you.

Study Treatment Group

You'll receive the combination of chemotherapy drugs being tested, **eribulin** and **gemcitabine**.

Your doctor will not have control over which group you will be assigned to. This helps make sure the study results are fair and reliable.

How long will I be in the trial?

You will be in the study for 3 years. Your study doctor will closely watch you for side effects and watch how the cancer responds to the treatment. You may continue treatment until it stops working or you have side effects that are too severe. You may choose to stop treatment at any time for any reason.

If you stop getting treatment, you will have follow-up visits with the study team until 3 years after you started the study.

Are there costs? Will I get paid?

The study drug eribulin is provided free in this study.

You will not be paid for joining the study. Check with your health care provider and insurance provider to find out what costs will and won't be covered in this study.

Where can I find more information about this trial?

- Talk with your health care provider
- Call the National Cancer Institute at **1-800-4-CANCER**
- Go to www.ClinicalTrials.gov and search the national clinical trial number: **NCT4579224**
- For a list of trial locations, visit swog.org/NCI-S1937

Key information

This trial is for adults 18 years or older being

Protocol number: S1937

Full trial title: A Phase III Randomized Trial of Eribulin (NSC #707389) with Gemcitabine versus Standard of Care (Physician's Choice) for Treatment of Metastatic Urothelial Carcinoma Refractory to, or Ineligible for, Anti PD1/PDL1 Therapy

NCT number: NCT04579224

Trial sponsor: SWOG Cancer Research Network

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Thank you!

When you join a clinical trial,
you're moving cancer medicine and patient care forward.