

Clinical trial summary (S1931)

Comparing the Outcome of Immunotherapy-Based Drug Combination Therapy with or without Surgery to Remove the Kidney in Metastatic Kidney Cancer



What is the purpose of this clinical trial?

This trial is for people who have metastatic kidney cancer (cancer that's spread to other places in the body). The study asks if adding surgery to the usual treatment with a combination of drugs can help patients live longer.

The study will compare 2 different treatment approaches:

Usual Treatment

standard systemic therapy (SST) using a combination of drugs

vs.

Study Treatment

standard systemic therapy (SST) using a combination of drugs

+

surgery to remove the kidney tumor and all or part of the kidney

The drug combination you'll get in the study will include at least 1 **immunotherapy** drug. Immunotherapy helps your immune system fight cancer.

This trial is set up to find out:

- If adding surgery to a standard combination of drugs can help people with metastatic kidney cancer live longer
- If adding surgery to a standard combination of drugs can help shrink the cancer
- What surgery complications and drug side effects people might have



Why is this trial important?

Most people with metastatic kidney cancer are treated with a combination of drugs that includes newer immunotherapy drugs. This study may help doctors learn whether adding surgery to these drug combinations helps patients live longer than treating them with the drugs alone.



Who can be in this trial?

This trial is for adults age 18 or older who have renal cell carcinoma, the most common type of kidney cancer.

This trial is for people who:

- Have metastatic cancer
- Have not received any immunotherapy drugs yet — or already received the treatment described in Step 1 below for 6 to 18 weeks

This trial is not for people who:

- Already had surgery to remove the kidney
- Have had a kidney transplant

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



What treatments will I get?

Step 1

Everyone in the study will get standard treatment with a combination of drugs. If you've already received treatment for 6 to 18 weeks (depending on which drug combination you're getting), you'll start the study at Step 2.

You and your doctor will decide which drug combination you'll get.

After you've received the drugs for about 12 weeks, you'll get an MRI or CT scan to check the cancer:

- **If the cancer has gotten worse**, your part in the study will be over. Talk with your doctor about other possible treatment options.
- **If the cancer is stable or has shrunk**, you'll move on to Step 2.

Step 2

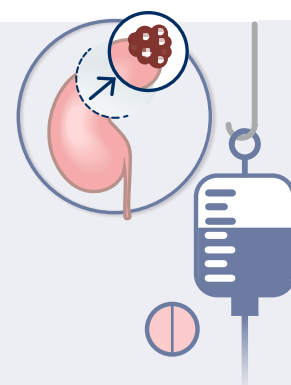
Group 1: standard drug combination

- You'll keep getting one of the standard treatments from Step 1.

or

Group 2: standard drug combination + kidney removal surgery

- You'll keep getting one of the standard treatments from Step 1.
- You'll have surgery to remove the tumor and all or part of a kidney.



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

All the drugs you'll receive during the study are approved by the FDA.



How long will I be in the trial?

If you move on to Step 2, you'll be in the study for **7 years** total. You'll keep receiving treatment until the cancer gets worse or the side effects get so bad that you decide to stop.

At first, you'll have visits with your study doctor every 3 months so they can see how you're doing and if the cancer has gotten worse. You'll have these visits less often over time.



Are there costs? Will I get paid?

To learn what costs will and won't be covered, talk to your health care provider and insurance provider.

You will not be paid for joining the 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: **NCT04510597**
- For a list of trial locations, visit swog.org/NCI-S1931



Key information

Protocol number: S1931

NCT number: NCT04510597

Trial sponsor: SWOG Cancer Research Network

Publishing date: July 23, 2025

Full trial title: Phase III Trial of Immunotherapy-Based Combination Therapy with or without Cytoreductive Nephrectomy for Metastatic Renal Cell Carcinoma (PROBE Trial)

Thank you!

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