

Clinical trial summary (S2419)

Adding biotherapy or placebo to standard treatment for advanced kidney cancer (BioFront Trial)

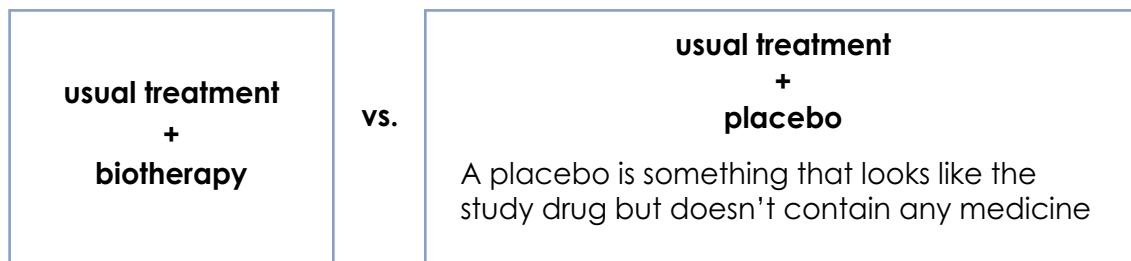


What is the purpose of this clinical trial?

This trial asks if adding a specific type of **biotherapy**, or probiotic, to the usual treatment for a type of advanced kidney cancer can help the usual treatment work better.

The usual treatment includes **immunotherapy**, which helps the immune system fight cancer. Biotherapy uses material from living organisms. The biotherapy in this study is a pill that contains a type of “good” bacteria.

The study will compare 2 treatment approaches:



This trial is set up to find out:

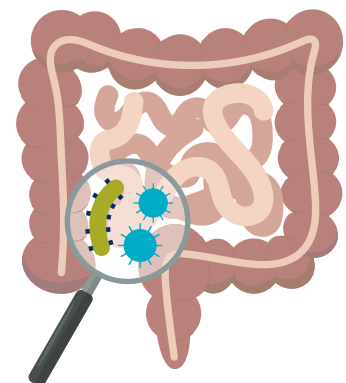
- If adding biotherapy to the usual treatment for advanced kidney cancer can help the usual treatment work better
- If adding biotherapy to the usual treatment can help people with advanced kidney cancer live longer
- What side effects combining biotherapy with the usual treatment can cause



Why is this trial important?

The gut microbiome is the collection of bacteria and other microscopic organisms that live in the human digestive system (gut). Studies have shown that the gut microbiome probably affects how well immunotherapy works.

This study looks at a biotherapy treatment that causes changes in the gut microbiome. It will help researchers learn if this treatment can help immunotherapy work better for people with advanced kidney cancer. The study could lead to new and better treatment options for people in the future.





Who can be in this trial?

This trial is for adults, age 18 and older, with a type of kidney cancer called clear cell renal cell carcinoma.

This trial is for people who:

- Have advanced cancer (cancer that's spread outside the kidneys or can't be treated with surgery or radiation alone)

This trial is not for people who:

- Are taking over-the-counter probiotic supplements
- Already received systemic therapy (like immunotherapy or targeted therapy) for advanced kidney cancer
- Are pregnant or breastfeeding

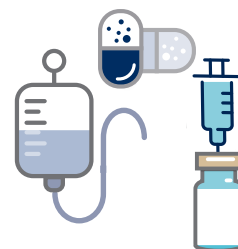


What treatments will I get?

A computer will randomly assign you to one of 2 study groups. Your doctor won't have control over which group you're assigned to. And you and your doctor won't know which group you're in until the study ends. This helps make sure the study results are fair and reliable.

You'll get:

- **The usual treatment for advanced kidney cancer: This could be one of several combinations of drugs**
- **Either biotherapy (a pill called MO-03) or a placebo pill**



You and your doctor will decide which usual combination of drugs is right for you:

- Every combination includes at least 1 immunotherapy drug.
- Some combinations also include a tyrosine kinase inhibitor (TKI). TKIs help stop cancer cells from growing.
- Some of the drugs are pills, and others are given through an IV (a needle placed in a vein in your arm) or as an injection (shot).

All of the usual combinations of drugs are approved by the FDA for treating kidney cancer. MO-03 is not approved by the FDA.



How long will I be in the trial?

You'll get treatment for up to 3 years, and you'll be in the study for up to 5 years total. After you stop treatment, you'll continue to have visits with your study doctor so they can see how you're feeling and if the cancer has gotten worse or come back.



Are there costs? Will I get paid?

The MO-03 and placebo are provided free in the study. To learn more about 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: **NCT07383441**
- For a list of trial locations, visit swog.org/NCI-S2419



Key information

Protocol number: S2419

NCT number: NCT07383441

Trial sponsor: SWOG Cancer Research Network

Publishing date: Publishing date: April 2, 2026

Full trial title: Phase III Double Blinded Trial of Immune-based Therapy with a Live Biotherapeutic MO-03 or Placebo for **Frontline** Therapy of Advanced Clear Cell Renal Cell Carcinoma (BioFront Trial)

Thank you!

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