

Clinical trial summary (S1922)

Treatment Options for People with Advanced Small Bowel Cancer



What is the purpose of this clinical trial?

This trial will test 2 treatments for a type of small bowel cancer called adenocarcinoma. This cancer is rare, and there is no standard treatment for it yet.

The study treatments have been approved by the Food and Drug Administration (FDA) for use in other cancers. Researchers want to find out if they also work for people with small bowel cancer.

Each of the study treatments combines different drugs. The combinations are:

- The drugs **ramucirumab** and **paclitaxel**
- The drugs **5-fluorouracil**, **leucovorin**, and **irinotecan** (this combination is known as **FOLFIRI**)

This trial is set up to find out:

- If the study treatments lower the chance of the cancer getting worse
- Which study treatment works better against this type of small bowel cancer
- What side effects people with small bowel cancer have from the study treatments



Why is this trial important?

Doctors often treat small bowel cancer with treatments that are used for similar cancers. But there hasn't been enough research yet to determine the best treatment approach.

This trial is a chance to find out if the study treatments work against small bowel cancer. If both study treatments work, the trial will help doctors learn which treatment is better for patients.



Who can be in this trial?

This trial is for adults, age 18 or older, with small bowel adenocarcinoma that has spread to nearby tissue, lymph nodes, or other places in the body.

This trial is for people who:

- Have cancer that got worse since treatment with the chemotherapy drugs fluoropyrimidine or oxaliplatin

This trial is not for people who:

- Already had treatment with taxane chemotherapy
- Already had treatment with the drugs ramucirumab or irinotecan
- Take long-term antiplatelet drugs (a type of blood thinner)
- 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

Group 1:

- Ramucirumab and paclitaxel

Group 2:

- FOLFIRI (5-fluorouracil, leucovorin, and irinotecan)

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 if you have side effects that are too severe. You may choose to stop treatment for any reason at any time.

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 drug ramucirumab is provided free in the 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 using the national clinical trial number: **04205968**



Key information *This trial is for adults 18 years or older being*

Full trial title: Randomized Phase II Selection Study of Ramucirumab and Paclitaxel versus FOLFIRI in Refractory Small Bowel

Protocol number: S1922

NCT number: 04205968

Trial sponsor: SWOG Cancer Research Network

Publishing date: April 20, 2023

Thank you!

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