

Can I take part?

You may be eligible to take part in PACES if

- you've had surgery for colon or rectal cancer within the past 4 - 15 months,
- you've completed any chemotherapy, and
- you are now cancer-free.

There are other eligibility requirements as well. Your study doctor or research nurse can review them with you to determine if you are eligible.



What will I be asked to do if I take part?

If you are eligible and decide to volunteer for the PACES trial, your participation will resemble something like the example below:

- ✓ Year 1: visit every three months for a physical exam and lab tests
- ✓ Years 2-3: visit every six months for a physical exam and lab tests
- ✓ Year 3: visit the center for a colonoscopy and hearing exam
- ✓ Years 4-7: one visit per year for a physical exam
- ✓ Year 8: visit for a routine colonoscopy

For more information,
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PACES
Preventing Adenomas of the Colon with Eflornithine & Sulindac

S0820 Colon Cancer Prevention Study for Colon & Rectal Cancer Survivors

PACES is a clinical trial that is seeking volunteers who have recently been treated for colon or rectal cancer. The goal is to learn whether taking the drugs eflornithine and sulindac can lower the risk of developing new adenomas (precancerous polyps) or a second primary colorectal cancer.

 **SWOG** | CANCER
RESEARCH
NETWORK

NCI National Clinical
Trials Network
a National Cancer Institute program

<https://www.swog.org/swog-study-s0820-patient-resources>

National Cancer Institute NCT01349881 SWOG-S0820

*This brochure does not replace the study's detailed informed consent form or information from your study doctor.
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How does this differ from the care I'll get if I don't take part in the PACES trial?

If you don't take part in this study, your follow-up care with your doctor will probably follow a similar schedule.

My colon or rectal cancer is gone. Why should I risk taking more drugs?

If you have already had colon cancer once, you are at higher risk of having another cancer. Most colon cancers start out as polyps.

What drugs are used in the trial?

Eflornithine is an investigational drug not otherwise available. Sulindac is approved for use as a nonsteroidal anti-inflammatory pain reliever and is sometimes used to treat arthritis pain. Both drugs are in pill form.

Who is conducting the trial?

PACES is being conducted by SWOG, a worldwide cancer network of researchers who conduct clinical trials. SWOG is a member of the National Clinical Trials Network.

Why were these drugs chosen?

An earlier study looked at the preventive effects of these drugs in people who had already had at least one colorectal polyp removed. Those who took this drug combination lowered their risk of developing another polyp over the next three years to less than one third of what it was for those who did not take the drugs. And they lowered their chances of developing a high-risk polyp during that time by 90%.

Will I see any benefits from taking part?

We hope that participants getting the two drugs will have a lower rate of high risk polyps. You will be closely monitored for any new polyps or cancer throughout your time on the trial.



Will everyone on the trial get the same drugs?

No. To learn whether the study drugs reduce colon or rectal cancer risk, researchers must compare a group of volunteers taking the drugs to a similar group of volunteers who take a placebo.

Neither you nor your doctor will know whether the pills you take are sulindac and eflornithine, or the matching placebos. You will be told at the end of the trial which pills you got.

How would taking part affect the cost of my care?

The drugs you take for the trial will be provided at no cost to you. You will also have two hearing tests at no cost to you.

The other tests and scans done during the trial are considered part of standard care and monitoring for colon cancer survivors. You or your insurance company will be billed (just as if you were not in a clinical trial). Insurance companies and Medicare generally cover the routine costs of care required within a clinical trial, but coverage varies from plan to plan. Check with your provider.