IRB Approved at
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PACES
Preventing Adenomas of the Colon with Eflornithine & Sulindac

Seeking Men and Women Who Have Had Colon or Rectal Cancer for a National Colon Cancer Prevention Trial

Purpose: To determine if the drugs, eflornithine and sulindac, can prevent the occurrence of high-risk colorectal polyps and new colorectal cancers in patients with previously treated colorectal cancer. People who have had colon or rectal cancer have a greater than average risk of developing polyps in the colon and rectum, which may become colon cancer in the future. Preventing polyps may reduce the risk of a new colorectal cancer.

You are eligible if you:

- have had stage 0, I, II, or III colon or rectal cancer
- had surgery for colorectal cancer within the past 4 – 15 months
- have completed any chemotherapy treatments are now cancer-free

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

WHAT DOES THE STUDY INVOLVE?

If you join the trial, you will be assigned at random to either take

- 2 tablets of eflornithine daily plus 1 tablet of sulindac daily or
- 2 tablets matching placebo for eflornithine plus 1 tablet matching placebo for sulindac daily.

The study drugs will be supplied free of charge and you will take it for three years.

WHY EFLORNITHINE AND SULINDAC?

Sulindac is a nonsteroidal, anti-inflammatory pain reliever commercially available but is not approved for this use. Eflornithine is an investigational drug currently not available outside of the clinical trial setting in the U.S. Eflornithine slows the production of a group of naturally-formed molecules called polyamines. Excess polyamines have a role in the development of colorectal cancer. Sulindac helps cells get rid of excess polyamines. Previous studies have shown that these drugs may reduce the chances of colon polyps or the development of a second colorectal cancer.

HOW LONG WILL PARTICIPANTS BE IN THE STUDY?

Participants will be in the study for a total of eight years. After three years of taking the study drugs, a member of our research team will continue to follow-up with you every 12 months until the eighth year.

CONTACT US

For more information about this trial, contact Perla Mota, RN at

773-564-5032 or at email pmota@weisshospital.com

SWOG CANCER RESEARCH NETWORK

NCI National Clinical Trials Network
a National Cancer Institute program

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