



S0820, "A Double Blind Placebo-Controlled Trial of Eflornithine and Sulindac to Prevent Recurrence of High Risk Adenomas and Second Primary Colorectal Cancers in Patients with Stage 0-III Colon or Rectal Cancer, Phase III - Preventing Adenomas of the Colon with Eflornithine and Sulindac (PACES)".

March 2017

PACES/S0820 is now a 2 arm trial per approved Amendment #2 Accrual goal is now 480 patients **WE CAN DO IT!**

Effective with recently approved Amendment #2, PACES/S0820 is now a 2-arm phase III trial of combination eflornithine/sulindac vs. combination placebo (E)/placebo (S). This new design will still address the question: Is there a role for these polyamine-inhibitory agents in the prevention of high-risk adenomas and 2nd primary colorectal cancers among CRC survivors? The prior phase III trial By Dr. Frank Meyskens demonstrated that 3-years of combination eflornithine/sulindac vs. placebo(E)/placebo(S) effectively reduced the adenoma recurrence rate by 70%, and the high-risk adenoma rate was decreased by >90%. However, effects among CRC survivors- who remain at risk for high-risk adenomas, 2nd primary CRCs, among other competing events- is not known.

Study participants registered to the single agent arms (eflornithine alone, or sulindac alone) will continue to be followed per protocol specifications. Data for these study participants will be analyzed for descriptive statistics to potentially inform future studies. This new design includes the same primary endpoint definition, and proposes a 50% reduction in our primary endpoint at 3-years for the combination active agents vs. combination placebos.

Pre-registration of Step 0 is still available to assist sites with tracking potential study participants. Updated recruitment materials are available at swog.org or on CTSU.

SWOG Study Co-Coordinator:
Jason A. Zell, DO, MPH
NRG Study Co-Coordinator:
Jennifer Dorth, MD
ECOG-ACRIN Study Co-Coordinator:
Raymond Bergan, MD
Alliance Study Co-Coordinator:
Nancy You, MD

Contact CancerControlQuestion@crab.org with study specific questions.
Contact Patricia O'Kane at pokane@swog.org with protocol questions.
Questions about accessing or navigating Medidata Rave, contact CTSU Help Desk at 1-888-823-5923 or ctscontact@westat.com