Protocol Title: Double Blind Placebo-Controlled Trial of Efornithine 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 Efornithine and Sulindac (PACES)

Target Population: Previously Treated Stage 0 – III Colorectal Cancer

Summary: The purpose of this study is to assess whether Efornithine 500 mg or Sulindac 150mg are effective in reducing the 3-year event rate of High Risk Adenoma or Second Primary Colorectal Cancer in Stage 0, I, II, and III Colon Cancer patients. The primary hypothesis will test the main effect of each agent, as well as the comparison of placebo alone to the combination of Sulindac and Efornithine.

Key Inclusion Criteria:
- History of Stage 0 - III Colon or Rectal Cancer with primary resection 1 Year previously.
- Postoperative Colonoscopy and CT Scans of Chest, Abdomen, and Pelvis showing no evidence of disease.
- Patients must not have known uncontrolled Hyperlipidemia within 28 Days prior to registration.
- At least 30 Days from completion of adjuvant chemotherapy and RT.
- Not receiving or planning to receive concomitant Corticosteroids, Nonsteroidal Anti-Inflammatory Drugs (NSAIDs), nor Anticoagulants.
  - Maximum Aspirin dose is 100mg per day or ≤ 2 325mg tablets per week.

Key Exclusion Criteria:
- History of Colon Resection > 40 cm.
- Mid-low Rectal Cancer.
- Known history of:
  - Familial Adenomatous Polyposis
  - Hereditary Nonpolyposis Colorectal Cancer
  - Inflammatory Bowel Disease
- ≥ 30 dB uncorrectable hearing loss for age of any of the five tested frequencies on pre-study audiogram.
- Known hypersensitivity to Sulindac or excipient byproducts.
  - Previous Asthma, Urticaria, or Allergic-type reaction to Aspirin or other NSAIDs.

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For additional information: https://clinicaltrials.gov/ct2/show/NCT01349881