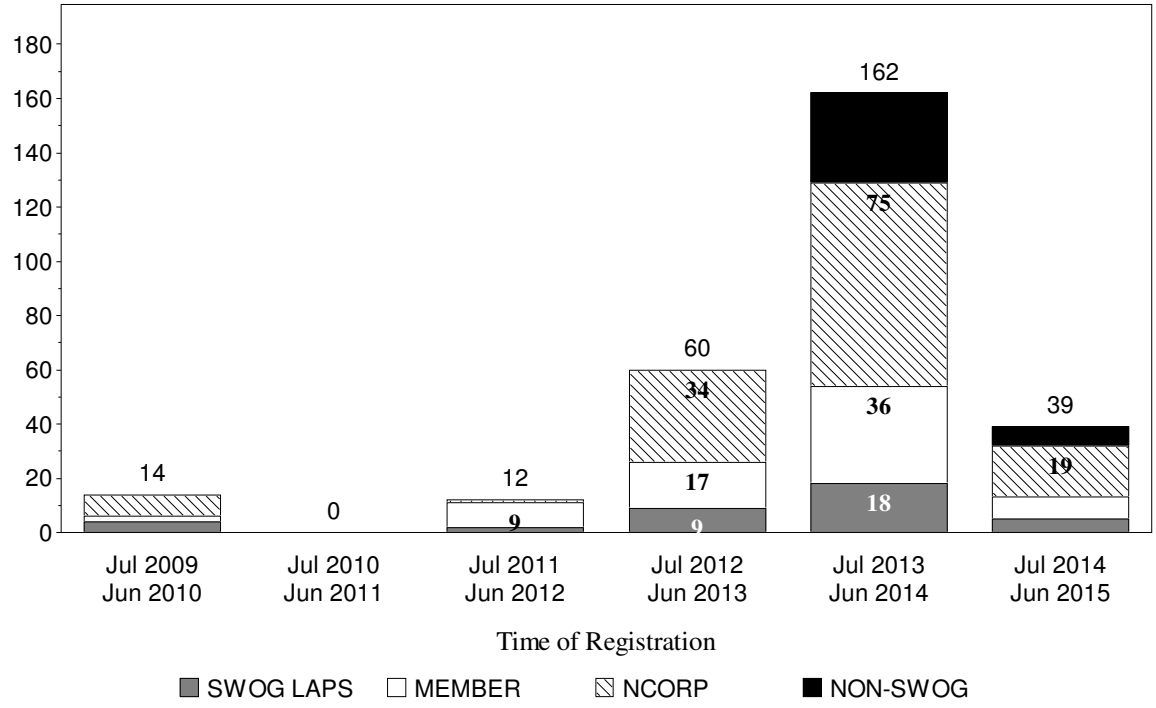
PREVENTION AND EPIDEMIOLOGY COMMITTEE

CONTENTS

Patient Registrations to Studies

By 12 Month Intervals
PREVENTION AND EPIDEMIOLOGY COMMITTEE



Screening registrations and registrations to Biologic only studies are excluded

Patient Registrations by Study and Arm

PREVENTION AND EPIDEMIOLOGY COMMITTEE

	Jan 2015 Jun 2015	Jul 2014 Dec 2014	Jan 2014 Jun 2014	All Patients
S0000B SELECT Eye Endpoints (SEE)				
Registration				
Registration	0	0	273	2,709
S0812 Breast, Prev, Vit D vs Placebo				
Initial Registration				
Blinded Drug (VitD or Placebo)	0	0	66	208
S0820 ColrecStg0-3 Blind DFMO/Sulindac				
Randomization				
Blinded drug	19	16	8	53
A211201 Breast Density, MA.32 companion*				
Total Registrations	0	4	4	12

* For non-SWOG coordinated studies only SWOG registrations are shown.

S0820 Phase III

Coordinating Group: SWOG

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)

Participants:
SWOG, CTSU

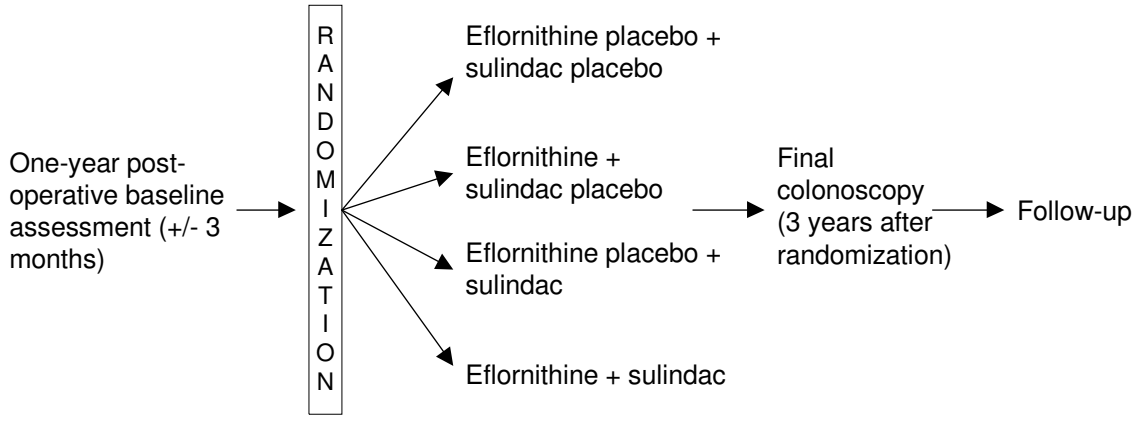
Date Activated:
03/01/2013

Study Chairs:
J Zell, P Brown

Statisticians:
J Unger, G Anderson, K Arnold

Data Coordinator:
M Yee

SCHEMA



Objectives

To assess whether eflornithine (+/- sulindac), sulindac (+/- eflornithine) or the combination are effective in reducing the three-year combined event rate (high-risk adenomas and second primary colorectal cancers) in patients with previously treated Stage 0-III colon or rectal cancer.

To assess whether eflornithine, sulindac or the combination has efficacy against colorectal lesions with respect to high-grade dysplasia, adenomas with villous features, adenomas 1 cm or greater, multiple adenomas, any adenomas $\geq$ 0.3 cm, total advanced colorectal events, or total colorectal events.

To assess quantitative and qualitative toxicities of patients when treated with eflornithine, sulindac, or the combination compared to placebo.

To evaluate a minimal set of tagging single nucleotide polymorphisms across multiple genes relevant to eflornithine and sulindac, in order to characterize associations with decreased adenoma/second primary colorectal cancer (CRC) risk and adverse events.

To examine the interaction of intervention arm and baseline statin use with respect to the three-year event rate.

To examine the interaction of the intervention arm and patient-reported meat consumption with respect to the 3-year event rate.

To perform pharmacokinetic (PK) analysis of eflornithine and sulindac in patients with previously treated Stage 0-III colon or rectal cancer.

Patient Population

Patients must have a history of Stage 0, I, II or III colon or rectal adenocarcinoma that has been treated per standard care with resection alone or in combination with radiation or chemotherapy. Adjuvant chemotherapy and/or radiation treatment must have been completed at least 30 days prior to registration.

Patients must be registered between 180 days and 456 days (inclusive) of primary resection. Patients must show no evidence of disease based on post-operative colonoscopy (performed at least 180 days after the colon resection date or at least 120 days after the rectal resection date and prior to registration) and CT or MRI scans (at the discretion of the treating physician for high risk patients, per NCCN guidelines) of chest, abdomen and pelvis (performed at least 180 days after the colon resection date or at least 120 days after the rectal resection date and prior to registration). Patients with adenomas detected at the one-year postoperative colonoscopy are eligible if all adenomas have been completely removed.

Patients must be at least 18 years of age and must not have cardiovascular risk factors as outlined in the protocol. Patients must have Zubrod performance status of 0-1 and adequate hematologic, hepatic and renal function. Patients must not have a known history of familial adenomatous polyposis, hereditary nonpolyposis colorectal cancer, or inflammatory bowel disease. Patients must have a pure tone audiometry evaluation within 30 days prior to registration: patients with at least 30 dB hearing loss of any of the tested frequencies are not eligible. Patients must not be hypersensitive to selective inhibitors of cyclooxygenase-2, non-steroidal anti-inflammatory drugs, salicylates, or sulfonamides. Patients must not have documented history of gastric/duodenal ulcer within the last 12 months.

Stratification/Descriptive Factors

At randomization, patients will be stratified by risk of recurrence: Stage 0/I vs Stage II with no prior chemotherapy vs Stage II with prior chemotherapy vs Stage III.

Accrual Goals

A total of 1,340 eligible patients will be enrolled, 335 to each study arm.

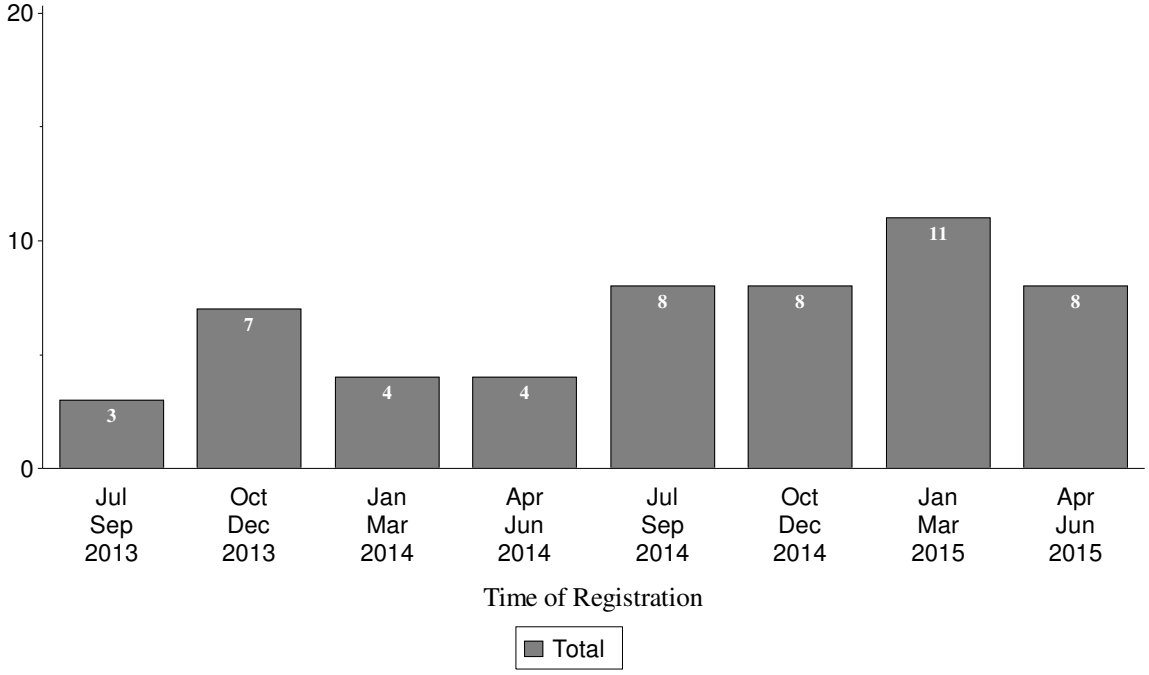
Summary Statement

This study activated on March 1, 2013. As of June 30, 2015, 53 patients have been registered to this study.

Two patients are ineligible due to high cardiovascular risk (1) and baseline hearing loss (1). Three patients who never started treatment were coded as major deviations; these patients were also not evaluable for adverse events. Seven patients are off treatment, five of whom refused further follow-up: two withdrew consent, two declined further participation, and one could not be contacted. No grade 3 or higher adverse events related to intervention have been reported.

Revision #4 incorporated multiple protocol changes, including opening the study to rectal cancer patients and allowing prior radiation therapy. Additionally, a tool for tracking patients from the time of initial resection to registration window is now available. As of August 26, 19 patients have been entered in the tracking tool.

Initial Registrations By 3 Month Intervals



Registration by Institution

Registrations ending June 30, 2015

Institutions	Total Reg	Institutions	Total Reg
Irvine, U of CA	8	Columbia MU-NCORP	1
Kaiser Vallejo NCORP	6	Columbus NCORP	1
Alliance	5	ECOG-ACRIN	1
MD Anderson CC	4	Heartland NCORP	1
San Antonio, U of TX	4	Highline Medical Ctr/Franciscan Res Ctr	1
Hawaii MU-NCORP	3	NE Georgia Med Ctr/Mississippi, Univ of	1
KaiserPermanenteSCAL/Kaiser Vallejo NCORP	3	Poudre Valley Hosp/Colorado, U of	1
So Calif, U of	3	St Joseph Hospital/Mississippi, Univ of	1
Kansas, U of	2	Wichita NCORP	1
McLaren Cancer Inst/Wayne State Univ	2	Yale University	1
NRG	2	**Total (22 Institutions)**	**53**
City of Hope Med Ctr	1		

Registration, Eligibility, and Evaluability

Registrations ending June 30, 2015; Data as of August 26, 2015

	Total
NUMBER REGISTERED	53
INELIGIBLE	2
ELIGIBLE	51
Analyzable, Pend. Elig.	1
ADVERSE EVENT ASSESSMENT	
Evaluable	41
Not Evaluable	3
Too Early	7

Patient Characteristics

Registrations ending June 30, 2015; Data as of August 26, 2015

	Total (n=51)	
AGE		
Median	52.1	
Minimum	29.2	
Maximum	73.6	
SEX		
Males	19	37%
Females	32	63%
HISPANIC		
Yes	5	10%
No	44	86%
Unknown	2	4%
RACE		
White	33	65%
Black	5	10%
Asian	10	20%
Pacific Islander	1	2%
Unknown	2	4%
RISK OF RECURRENCE		
Stage 0 or I	8	16%
Stage II with no prior chemotherapy or radiation therapy	9	18%
Stage II with prior chemotherapy or radiation therapy	4	8%
Stage III	30	59%

Intervention Summary

Registrations ending June 30, 2015; Data as of August 26, 2015

	Total
NUMBER ON PROTOCOL INTERVENTION	44
NUMBER OFF PROTOCOL INTERVENTION	7
REASON OFF INTERVENTION	
Intervention completed as planned	0
Adverse Event or side effects	1
Refusal unrelated to adverse event	5
Progression/relapse	1
Death	0
Other - not protocol specified	0
Reason under review	0
MAJOR PROTOCOL DEVIATIONS	3

Number of Patients with a Given Type and Grade of Adverse Event

Adverse Events Unlikely or Not Related to Intervention Excluded

Registrations ending June 30, 2015; Data as of August 26, 2015

			Total (n=41) Grade			
ADVERSE EVENTS	**0**	**1**	**2**	**3**	**4**	**5**
ALT increased	39	2	0	0	0	0
AST increased	40	1	0	0	0	0
Abdominal pain	40	0	1	0	0	0
Alkaline phosphatase increased	40	1	0	0	0	0
Alopecia	40	1	0	0	0	0
Bloating	40	0	1	0	0	0
Blood bilirubin increased	40	1	0	0	0	0
Chest pain - cardiac	40	1	0	0	0	0
Constipation	33	6	2	0	0	0
Diarrhea	36	4	1	0	0	0
Dizziness	38	3	0	0	0	0
Dry mouth	40	1	0	0	0	0
Dysphagia	40	1	0	0	0	0
Dyspnea	40	1	0	0	0	0
Fatigue	39	2	0	0	0	0
GERD	40	1	0	0	0	0
Gastrointestinal pain	40	1	0	0	0	0
Headache	39	2	0	0	0	0
Hot flashes	39	2	0	0	0	0
Hyperglycemia	40	0	1	0	0	0
Hypertension	40	0	1	0	0	0
Insomnia	40	0	1	0	0	0
Irregular menstruation	40	1	0	0	0	0
Nausea	37	4	0	0	0	0
Rash maculo-papular	40	1	0	0	0	0
Rectal hemorrhage	40	1	0	0	0	0
Somnolence	40	1	0	0	0	0
MAX. GRADE ANY ADVERSE EVENT	21	13	7	0	0	0