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Oxaliplatin, Leucovorin, and Fluorouracil With or Without Bevacizumab in Treating Patients Who Have Undergone Surgery for Stage II Colon Cancer

ClinicalTrials.gov ID NCT00217737

Sponsor National Cancer Institute (NCI)

Information provided by National Cancer Institute (NCI) (Responsible Party)

Last Update Posted 2025-07-20

Results Posted Tab

Results Overview

Conditions

Colon Adenocarcinoma | Stage IIA Colon Cancer AJCC v7 | Stage IIB Colon Cancer AJCC v7 | Stage IIC Colon Cancer AJCC v7

Intervention/Treatment

- Biological: Bevacizumab
- Drug: Fluorouracil
- Drug: Leucovorin
- Drug: Oxaliplatin

Other Study ID Numbers

Enrollment (Actual)

2431

Study Type

Interventional

- NCI-2009-00562 (Registry Identifier) (REGISTRY: CTRP (Clinical Trial Reporting Program))
- 05-198
- CDR0000443410
- **E5202**
- ECOG-**E5202**
- **E5202** (Other Identifier) (OTHER: ECOG-ACRIN Cancer Research Group)
- **E5202** (Other Identifier) (OTHER: CTEP)
- U10CA021115 (U.S. NIH Grant/Contract) (https://reporter.nih.gov/quickSearch/U10CA021115)
- U10CA180820 (U.S. NIH Grant/Contract) (https://reporter.nih.gov/quickSearch/U10CA180820)

Study Design

Allocation ⓘ**:** Randomized

Interventional Model ⓘ**:** Parallel Assignment

Masking ⓘ**:** None (Open Label)

Primary Purpose ⓘ**:** Treatment

Results Point of Contact

Name/Title: Study Statistician
Organization: ECOG-ACRIN Statistical Office
Phone: 617-632-3012
Email: eatrials@jimmy.harvard.edu

Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

Study Registration Dates		Results Reporting Dates		Study Record Updates	
First Submitted	2005-09-20	**Results First Submitted**	2025-05-27	**Last Update Posted**	2025-07-20
First Posted (Estimated)	2005-09-22	**Results First Posted**	2025-07-20	**Last Verified**	2025-07

Participant Flow

Recruitment Details	The study was activated on August 4th, 2005 and was closed to accrual on February 11th, 2011. A total of 2,431 patients were enrolled.
Pre-assignment Details	[Not Specified]

Arm/Group Title	Arm A (5-FU, Leucovorin, Oxaliplatin)	Arm B (5-FU, Leucovorin, Oxaliplatin, Bevacizumab)	Arm C (Observation)
Arm/Group Description	Patients receive oxaliplatin IV over 2 hours and leucovorin calcium IV over 2 hours on day 1. Patients also receive fluorouracil IV continuously over 46 hours beginning on day 1. Treatment repeats every 2 weeks for 12 courses in the absence of disease progression or unacceptable toxicity.	Patients receive oxaliplatin, leucovorin calcium, and fluorouracil as in Arm A and bevacizumab IV over 30-90 minutes on day 1. Treatment repeats every 2 weeks for 12 courses in the absence of disease progression or unacceptable toxicity. Patients then receive bevacizumab alone for 12 additional courses in the absence of disease progression or unacceptable toxicity.	Patients undergo observatior

Expand

Period Title: **Step 1 Registration (Risk Assessment)**

Started	460	458	1013
Completed	460	458	1013
Not Completed	0	0	0

Reason Not Completed

Withdrawal by Subject	0	0	0
No tumor block assessments	0	0	0
Ineligible	0	0	0
Uninformative tumor block	0	0	0
Physician Decision	0	0	0
Study suspension/closure before treatment	0	0	0
Staff/site error	0	0	0
Unable to follow treatment schedule	0	0	0
Adverse Event	0	0	0
Insurance issues	0	0	0
Non-compliance	0	0	0
Death	0	0	0
Disease progression	0	0	0

Inadequate supply of Leucovorin	0	0	0
Lost to Follow-up	0	0	0
Other	0	0	0
Registration error	0	0	0

Period Title: **Step 2 Randomization/Registration**

Started	460	458	1013
Eligible Patients	424	435	998
Received Treatment	429	410	0
Received Treatment and Toxicity Data Available	428	410	0
Included in the Analysis of Impact of Tumor Biological Characteristics on Survival	326	324	718
Completed	304	143	1013
Not Completed	156	315	0

Reason Not Completed

Adverse Event	59	98	0
Withdrawal by Subject	53	105	0
Study suspension	0	45	0
Complicating disease	5	5	0
Death	2	3	0
Non-compliant	2	4	0
Physician Decision	2	2	0
Alternative therapy	0	1	0
Extraordinary Medical Circumstances	0	1	0
Found to be Ineligible After Treatment	0	1	0
Incorrect Cancer Stage	1	0	0
Never started protocol therapy	31	48	0
Other	1	2	0

Baseline Characteristics

Arm/Group Title	Arm A (5-FU, Leucovorin, Oxaliplatin)	Arm B (5-FU, Leucovorin, Oxaliplatin, Bevacizumab)	Arm C (Observation)
Arm/Group Description	Patients receive oxaliplatin IV over 2 hours and leucovorin calcium IV over 2 hours on day 1. Patients also receive fluorouracil IV continuously over 46 hours beginning on day 1. Treatment repeats every 2 weeks for 12 courses in the absence of disease progression or unacceptable toxicity.	Patients receive oxaliplatin, leucovorin calcium, and fluorouracil as in Arm A and bevacizumab IV over 30-90 minutes on day 1. Treatment repeats every 2 weeks for 12 courses in the absence of disease progression or unacceptable toxicity. Patients then receive bevacizumab alone for 12 additional courses in the absence of disease progression or unacceptable toxicity.	Patients undergo observatior
Overall Number of Baseline Participants	460	458	1013
Baseline Analysis Population Description	All patients registered to Step 2 are included in this analysis.		

Expand

Age, Continuous

Median (Full Range) | Unit of measure: years

Number Analyzed	460 participants	458 participants	1013 participants
	59 (26 to 87)	59 (25 to 85)	60 (19 to 90)

Sex: Female, Male [1]

Measure Type: Count of Participants | Unit of measure: Participants

Number Analyzed	459 participants	458 participants	1013 participants
Female	235 51.2%	232 50.7%	496 49.0%
Male	224 48.8%	226 49.3%	517 51.0%

[1] Measure Analysis Population Description: One patient with unknown sex was excluded from the analysis of distribution of sex.

Ethnicity (NIH/OMB)

Measure Type: Count of Participants | Unit of measure: Participants

Number Analyzed	460 participants	458 participants	1013 participants
Hispanic or Latino	29 6.3%	32 7.0%	88 8.7%
Not Hispanic or Latino	401 87.2%	390 85.2%	868 85.7%

Unknown or Not Reported	30 6.5%	36 7.9%	57 5.6%

Race (NIH/OMB)

Measure Type: Count of Participants | Unit of measure: Participants

Number Analyzed	460 participants	458 participants	1013 participants
American Indian or Alaska Native	1 0.2%	2 0.4%	0 0.0%
Asian	17 3.7%	14 3.1%	32 3.2%
Native Hawaiian or Other Pacific Islander	0 0.0%	0 0.0%	0 0.0%
Black or African American	49 10.7%	55 12.0%	85 8.4%
White	385 83.7%	372 81.2%	882 87.1%
More than one race	2 0.4%	0 0.0%	0 0.0%
Unknown or Not Reported	6 1.3%	15 3.3%	14 1.4%

Outcome Measures

Expand all / Collapse all

1. Disease-free Survival Rate at 5 Years

Type: Primary | Time Frame: Assessed every 3 months for patients within 2 years of step 2 randomization, every 6 months during 3-5 years from step 2 randomization, and then every 12 months until 10 years from step 2 randomization

Description	Disease-free survival (DFS) is defined as the time from randomization to the earlier of disease recurrence, new invasive primary cancer, or death from any cause. The Kaplan-Meier estimates were used to characterize the 5-year DFS rates.
Time Frame	Assessed every 3 months for patients within 2 years of step 2 randomization, every 6 months during 3-5 years from step 2 randomization, and then every 12 months until 10 years from step 2 randomization
Analysis Population Description	Eligible patients who were registered or randomized at Step 2 were included in this analysis.

Arm/Group Title	Arm A (5-FU, Leucovorin, Oxaliplatin)	Arm B (5-FU, Leucovorin, Oxaliplatin, Bevacizumab)	Arm C (Observation)
Arm/Group Description	Patients receive oxaliplatin IV over 2 hours and leucovorin calcium IV over 2 hours on day 1. Patients also receive fluorouracil IV continuously over 46 hours beginning on day 1. Treatment repeats every 2 weeks for 12 courses in the absence of disease progression or unacceptable toxicity.	Patients receive oxaliplatin, leucovorin calcium, and fluorouracil as in Arm A and bevacizumab IV over 30-90 minutes on day 1. Treatment repeats every 2 weeks for 12 courses in the absence of disease progression or unacceptable toxicity. Patients then receive bevacizumab alone for 12 additional courses in the absence of disease progression or unacceptable toxicity.	Patients undergo observatior
Overall Number of Participants Analyzed	424	435	998
Measure Type: Number (95% Confidence Interval) | Unit of Measure: Proportion of participants	0.805 (0.766 to 0.846)	0.833 (0.796 to 0.871)	0.816 (0.791 to 0.842)

Statistical Analysis 1

Statistical Analysis Overview

Comparison Group Selection	Arm A (5-FU, Leucovorin, Oxaliplatin), Arm B (5-FU, Leucovorin, Oxaliplatin, Bevacizumab)
Comments	[Not Specified]
Type of Statistical Test	Superiority
Comments	[Not Specified]

Method of Estimation

Estimation Parameter	Hazard Ratio (HR)
Estimated Value	0.83
Confidence Interval	(2-Sided) 95% 0.63 to 1.11
Estimation Comments	Hazard ratio: Arm B/Arm A

2. Overall Survival Rate at 5 Years

Type: Secondary | Time Frame: Assessed every 3 months for patients within 2 years of step 2 randomization, every 6 months during 3-5 years from step 2 randomization, and then every 12 months until 10 years from step 2 randomization

Description	Overall survival (OS) is defined as the time from randomization to death from any cause. OS is censored at the date of last contact for patients still alive. The Kaplan-Meier estimates were used to characterize the 5-year OS rates.
Time Frame	Assessed every 3 months for patients within 2 years of step 2 randomization, every 6 months during 3-5 years from step 2 randomization, and then every 12 months until 10 years from step 2 randomization
Analysis Population Description	Eligible patients who were registered or randomized at Step 2 were included in this analysis.

Arm/Group Title	Arm A (5-FU, Leucovorin, Oxaliplatin)	Arm B (5-FU, Leucovorin, Oxaliplatin, Bevacizumab)	Arm C (Observation)
Arm/Group Description	Patients receive oxaliplatin IV over 2 hours and leucovorin calcium IV over 2 hours on day 1. Patients also receive fluorouracil IV continuously over 46 hours beginning on day 1. Treatment repeats every 2 weeks for 12 courses in the absence of disease progression or unacceptable toxicity.	Patients receive oxaliplatin, leucovorin calcium, and fluorouracil as in Arm A and bevacizumab IV over 30-90 minutes on day 1. Treatment repeats every 2 weeks for 12 courses in the absence of disease progression or unacceptable toxicity. Patients then receive bevacizumab alone for 12 additional courses in the absence of disease progression or unacceptable toxicity.	Patients undergo observatior
Overall Number of Participants Analyzed	424	435	998
Measure Type: Number (95% Confidence Interval) | Unit of Measure: Proportion of participants	0.918 (0.891 to 0.946)	0.921 (0.895 to 0.948)	0.926 (0.909 to 0.943)

3. The Impact of Tumor Biological Characteristics on Overall Survival

Type: Secondary | Time Frame: Assessed at baseline, every 3 months for patients within 2 years of step 2 randomization, every 6 months during 3-5 years from step 2 randomization, and then every 12 months until 10 years from step 2 randomization

Description	Overall survival (OS) is defined as the time from randomization to death from any cause. OS is censored at the date of last contact for patients still alive. The following patient/tumor characteristics were associated with overall survival: • ECOG Performance Status (0, 1, or 2) • Age • Sex (male, female) • Primary tumor site (right-side colon, transverse colon, left-side colon, or other) • Number of regional lymph nodes Hazard ratios with adjustment for other covariates are reported with OS as the outcome variable.
Time Frame	Assessed at baseline, every 3 months for patients within 2 years of step 2 randomization, every 6 months during 3-5 years from step 2 randomization, and then every 12 months until 10 years from step 2 randomization
Analysis Population Description	Eligible patients who had advanced to step 2 (Arms A, B and C) and had complete data on patient/tumor characteristics are included.

Arm/Group Title	Tumor Biological Characteristics and Overall Survival Analysis
Arm/Group Description	Eligible patients who had advanced to step 2 (Arms A, B and C) and had complete data on patient/tumor characteristics are included.
Overall Number of Participants Analyzed	1368
Hazard ratio: ECOG performance status of 1 (vs. 0) ∗Measure Type: Number (95% Confidence Interval) | Unit of Measure: hazard ratio	1.67 (1.24 to 2.25)
Hazard ratio: ECOG performance status of 2 (vs. 0) *	3.39 (1.36 to 8.44)
Hazard ratio: Age *	1.05 (1.04 to 1.07)
Hazard ratio: Sex of male (vs. female) *	1.71 (1.27 to 2.28)
Hazard ratio: Primary site of transverse colon (vs. Right-side colon) *	0.81 (0.44 to 1.52)

Hazard ratio: Primary site of left-side colon (vs. Right-side colon) *	1.13 (0.82 to 1.55)
Hazard ratio: Primary site of other (vs. Right-side colon) *	2.68 (1.39 to 5.17)
Hazard ratio: Number of lymph nodes *	0.98 (0.96 to 0.99)

* Measure Type: Number (95% Confidence Interval) | Unit of Measure: hazard ratio

etween Oxaliplatin Exposure, Allelic Variants in Candidate Genes, and Neurotoxicity

d | Time Frame: Assessed at baseline, every 2 weeks while on treatment, up to 10 years

Description	The association between onset of neurotoxicity and oxaliplatin exposure will be assessed. The difference in neurotoxicity rates between patients with and without a given polymorphism will be evaluated.
Time Frame	Assessed at baseline, every 2 weeks while on treatment, up to 10 years
Analysis Population Description	[Not Specified]

Outcome Measure Data Not Reported

Adverse Events

Time Frame	Assessed every 2 weeks while on treatment and for 30 days after the end of treatment, up to 10 years
Adverse Event Reporting Description	All patients received treatment at Step 2 and had adverse event data were included in the analysis of adverse events. Patients who underwent observation in

	Arm C did not receive any treatment, so no adverse event data were collected for these patients. All patients registered/randomized at Step 2 were included in the analysis of all-cause mortality.

Serious Adverse Events

Arm/Group Title	Arm A (5-FU, Leucovorin, Oxaliplatin)	Arm B (5-FU, Leucovorin, Oxaliplatin, Bevacizumab)	Arm C (Observation)

1	Term from vocabulary, CTCAE 4.0

Limitations and Caveats

[Not Specified]

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

National Cancer Institute (NCI)

Investigators

- Principal Investigator: Al B Benson, ECOG-ACRIN Cancer Research Group

More Information

Record History

Certain Agreements

Principal Investigators are NOT employed by the organization sponsoring the study.

There IS an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed