93-246

DRE1.940922.025

PROTOCOL SUMMARY

Title: RTOG #92-03: A Phase III Study of Radiation Therapy, Levamisole and 5-Fluorouracil vs 5-Fluorouracil and Levamisole in Selected Patients with Completely Resected Colon Cancer

Principal Investigator: [redacted] Capt, USAF, MC/PSMH/2-7312

Facility: Wilford Hall Medical Center

1. **SUMMARY:** Colon cancer is a major cause of cancer-related morbidity and mortality in the United States with approximately 110,000 cases anticipated in 1990 and 53,330 deaths. Colon cancer is a disease which is treated primarily with surgery. Patients who are found to have positive regional lymph nodes (Dukes C, colon cancer) are at increased risk for relapse. Adjuvant therapy of these individuals with 5-FU and levamisole has been shown to resolve in a survival advantage. In addition to the risk of systemic relapse, there is a risk of local regional recurrence. In Dukes C colon cancer patients who have a primary tumor which penetrates through the colonic wall, there is approximately a 37% incidence of local regional failure. In patients with a tumor which adheres to or invades surrounding structures (Dukes B3, C3), the risk of local regional occurrence is even higher, about 67%. It is hypothesized that the addition of radiation therapy to standard adjuvant chemotherapy could result in improved local regional control and, hopefully, an improved overall survival.

This protocol is a Phase III randomized study comparing adjuvant chemotherapy alone with 5-FU and levamisole to the same adjuvant chemotherapy plus 4500 C of radiation therapy to the tumor bed in patients who have locally advanced primary tumors manifested by either adherence to or invasion of surrounding structures; or penetration through the wall into the retroperitoneum with positive regional lymph nodes. Five patients, age 18 and older, will be enrolled from Wilford Hall Medical Center each year.

The primary goal of this study is to assess the addition of radiation to adjuvant chemotherapy with regards to overall survival. Secondary endpoints include disease-free survival, patterns of failure, and the toxicity of the regimen.

2. **INVESTIGATIONAL DRUGS/DEVICES:** None

3. **LABORATORY, RADIOLOGY, OR OTHER SPECIAL SUPPORT REQUIRED:** Assuming 5 patients are enrolled over the next year, the following number of tests will be required:

TEST NAME	STD OF CARE (Y/N)	TYPE OF SPECIMEN	QUANTITY	TIME FRAME LENGTH OF STUDY
CBC	Y	blood	90	1st year
$7, LFTs	Y	blood	20	year
CEA	Y	blood	20	year
Chest X-ray, PA and Lateral	Y	X-ray	20	year
Abdominal CT	Y	X-ray	10	year

This lab work is not in excess of that required for standard oncologic care.

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FUNDING: N/A

INVESTIGATOR CATEGORIES: Principal Investigator - 1 Fellow; Associate Investigators - 12 Staff and Fellows

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