

**4800497**

**PROTOCOL SUMMARY**

**Title:** SWOG #9216, INT-0131, A Randomized Phase III Study of CODE Plus Thoracic Irradiation Versus Alternating CAV and EP for Extensive Stage Small Cell Lung Cancer

**Principal Investigator:** [REDACTED] Major, USAF, MC/PSMH/2-7312

**Facility:** Wilford Hall Medical Center

1. **SUMMARY:** Small cell lung cancer affects approximately 40,000 patients per year in the United States and nearly all of those patients will die from the disease. In addition, a high percentage of patients with this type of lung cancer present with widely metastatic disease. Currently chemotherapy is used in all patients to prolong median survival. In untreated patients with small cell lung cancer, survival is currently 4-6 weeks. The addition of chemotherapy has lengthened survival to currently somewhere between 6-9 months, but patients continue to die from local disease as well as CNS metastasis. There are only a handful of patients with extensive small cell lung cancer that are alive after several years. In an attempt to improve the overall survival and response rate of patients with extensive small cell lung cancer, this study will compare a standard combination of drugs currently used for small cell lung cancer with a similar combination of drugs plus the addition of radiation to see if the percentage of patients achieving a complete remission can be increased and overall survival can be increased. In addition, this protocol will examine side effects from combinations of chemotherapy with radiation versus combination chemotherapy alone. Finally, patients will be asked to participate in filling out a quality of life questionnaire to determine how they are feeling while they are undergoing this treatment. The two treatment arms will consist of either treatment with standard care chemotherapy which will consist of cyclophosphamide, doxorubicin, and vincristine (CAV), alternating with etoposide and cisplatin (EP), or cisplatin, vincristine, doxorubicin, and etoposide (CODE). Patients who achieve a complete remission on CODE therapy will go on to receive thoracic irradiation and prophylactic cranial irradiation. Approximately 5-10 adult patients will be enrolled annually from Wilford Hall Medical Center.

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

3. **LABORATORY, RADIOLOGY, OR OTHER SPECIAL SUPPORT REQUIRED:** All support will be standard of care items associated with standard oncological care for this group of patients with extensive small cell lung cancer.

4. **FUNDING:** None

5. **INVESTIGATOR CATEGORIES:** Principal Investigator - 1 Staff; Associate Investigators - 7 Staff and 10 Fellows

6. **MISCELLANEOUS:** None

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