

1 Precis

This is a Phase I trial of a 12-21 day course of oral etoposide plus cisplatin with BID chest radiotherapy for patients with untreated limited stage small cell lung cancer (SCLC). Patients will be treated with increasing doses of oral etoposide until the maximum tolerated dose of etoposide cisplatin with a concurrent course of chest radiotherapy at a dose of 45 Gy is determined. Then the dose of chest radiotherapy will be escalated to determine the maximal tolerated dose of chest radiation. After completion of the concurrent combined modality therapy, patients will be treated with cyclophosphamide, doxorubicin, and etoposide alternating with etoposide cisplatin for a total of six months of therapy. In addition to the concurrent treatment, patients will be offered the opportunity to undergo a biopsy to have their tumor tissue studied for the presence of p53 gene mutations. If the patients have a p53 mutation and relapse with small cell lung cancer, they will be offered the opportunity to participate in a previously approved protocol (MB-272) studying the vaccination of patients with mutated p53 peptide incubated with their own lymphocytes.

2 SCHEMA

WEEK

- 0 Staging investigations and tissue procurement
- 1 Etoposide orally days 1 through 12 or 21
Cisplatin administration day 1
- 1-3 Chest Radiotherapy
- 5 Repeat etoposide and cisplatin
- 8 CAVP-16
- 11 Repeat etoposide cisplatin
- 15 Repeat CAVP-16
- 18 Repeat etoposide cisplatin
- 22 Repeat CAVP-16
- 25 Restage and administer prophylactic cranial irradiation if patients are in complete response.