

PHASE III COMPARISON OF THORACIC RADIOTHERAPY REGIMENS WITH CISPLATIN AND ETOPOSIDE IN LIMITED SMALL CELL LUNG CANCER

Patient Eligibility

Histologically or cytologically documented small cell lung cancer of limited stage (see Section 4.1).
 Measurable or non-measurable disease.
 No prior chemotherapy or radiotherapy for SCLC.
 No prior mediastinal or thoracic radiotherapy
 Patients with complete surgical resection of disease are not eligible.
 Age ≥18 years.
 ECOG Performance status 0-2.
 Non-pregnant and non-nursing.

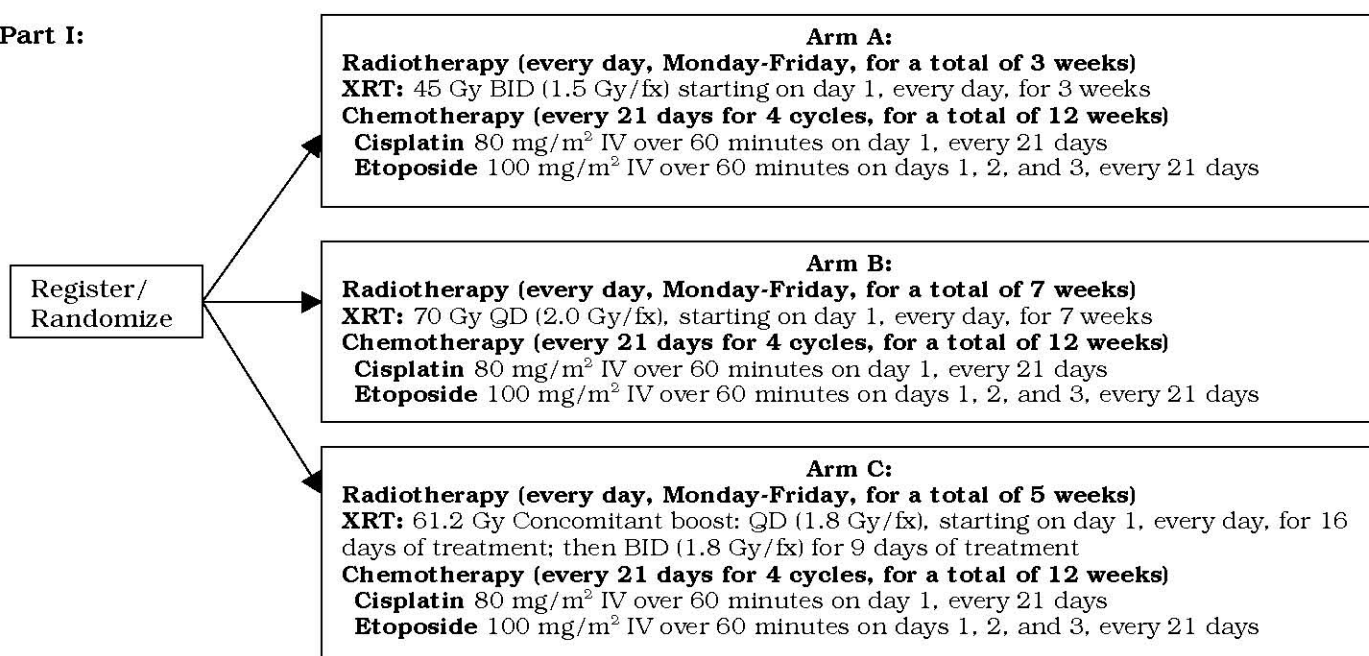
Required Initial Laboratory Values

Granulocytes ≥1,500/ μ l
 Platelets ≥100,000/ μ l
 Total Bilirubin ≤1.5 x ULN
 AST (SGOT) ≤2.0 x ULN
 Serum Creatinine ≤ 1.5 x ULN
 OR
 Calculated CrCl ≥ 70 ml/min

Schema (1 cycle = 21 days)

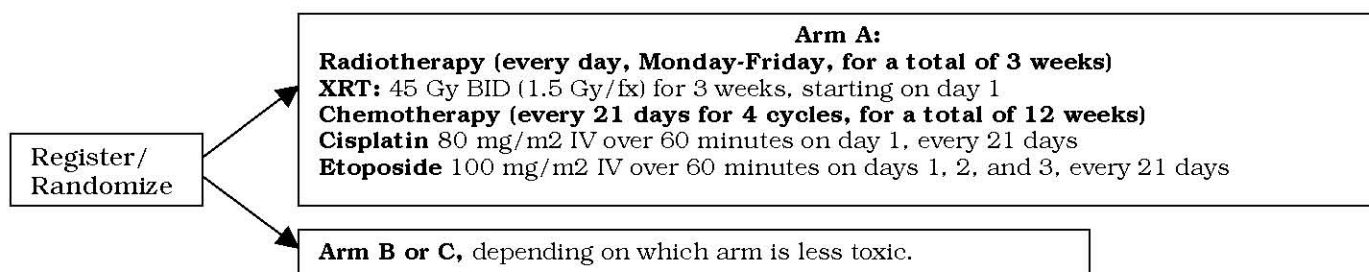
Patients will receive 4 cycles of chemotherapy on all arms

Part I:



Prophylactic cranial irradiation (PCI) should be offered to all patients with a complete or near complete response (see Section 8.2.9 for further details).

Part II: Based on the results of Part I, the experimental arm with the higher rate of toxic events will be discontinued and patients will be randomized as follows:



Prophylactic cranial irradiation (PCI) should be offered to all patients with a complete or near complete response (see Section 8.2.9 for further details).