

**Phase I study of etoposide, cisplatin and irinotecan triplet in patients with advanced-stage small-cell lung cancer.**

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**Source**

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**Abstract**

**AIM:**

The irinotecan-cisplatin combination has emerged as a new standard for the treatment of advanced-stage small-cell lung cancer (AS-SCLC). To move forward we developed a 3-day regimen of cisplatin, etoposide and irinotecan.

**METHODS:**

Successive cohorts of AS-SCLC patients were treated with irinotecan administered as a single 1-h infusion in combination with fixed doses of cisplatin (20 mg/m<sup>2</sup>) and etoposide (75 mg/m<sup>2</sup>), both given for three consecutive days (ECI regimen). Irinotecan dose was escalated from 60 mg/m<sup>2</sup> by 40-mg/m<sup>2</sup> increments. At mid-step between the maximum tolerated dose (MTD) and the previous dose level, patients were randomized for the day of administration of irinotecan (day 1 vs day 3).

**RESULTS:**

A total of 36 AS-SCLC patients received 166 courses of treatment at four dose levels. The MTD of irinotecan was 140 mg/m<sup>2</sup> (three dose-limiting toxicities, DLTs), and the recommended optimal dose (ROD) 120 mg/m<sup>2</sup> (two DLTs). DLTs were febrile neutropenia and grade 3 diarrhea. Other toxicities were mild. No difference in toxicity was seen between the two time schedules. A 77% (95% CI 63.25-90.75%) response rate was recorded among 31 evaluable patients and the median survival was 12 months.

**CONCLUSIONS:**

The ECI regimen was well tolerated and showed considerable activity in patients with AS-SCLC. Phase II/III evaluation is ongoing.