



Figure 2.8 Schema showing a 2-arm study. In this 2-arm study drugs were administered in a “forward” sequence for arm A, and in a “reverse” sequence for arm B

f. Both arms received three drugs, each arm at a different schedule – the Sekine schema

In a clinical trial of lung cancer, Sekine et al. (40) administered three drugs to all subjects in arm A and the same three drugs to all subjects in arm B (Fig. 2.9). Different schedules were used for each of the three drugs. The two arms were different from each other in that different schedules were used for administering the drugs.

The three drugs shown on the schema, cisplatin, irinotecan, and etoposide, are small molecule drugs. Subjects also received a fourth drug, granulocyte colony stimulating factor (G-CSF). G-CSF is a polypeptide, not a small molecule. For clarity in presentation G-CSF is not shown on the schema. Blood samples and chest X-rays were taken at various intervals (not shown). Blood counts were run twice a week, and chest X-rays were conducted once a week. Chest X-rays are used during the diagnosis and treatment of lung cancer (41).

g. Staging – the Blumenschein schema

The schema of Blumenschein et al. (42) reveals three different steps in the trial design (Fig. 2.10). These are the step of stratifying patients according to disease stage, the step of randomization, and the step of drug administration. Although most clinical trials in

⁴⁰ Sekine I, Nishiwaki Y, Noda K, et al. Randomized phase II study of cisplatin, irinotecan and etoposide combinations administered weekly or every 4 weeks for extensive small-cell lung cancer (JCOG9902-DI). *Ann Oncol.* 2003;14:709–714.

⁴¹ Gohagan JK, Marcus PM, Fagerstrom RM, et al. Final results of the Lung Screening Study, a randomized feasibility study of spiral CT versus chest X-ray screening for lung cancer. *Lung Cancer.* 2005;47:9–15.

⁴² Blumenschein Jr. GR, Khuri FR, von Pawel J, et al. Phase III trial comparing carboplatin, paclitaxel, and bexarotene with carboplatin and paclitaxel in chemotherapy-naïve patients with advanced or metastatic non-small-cell lung cancer: SPIRIT II. *J Clin Oncol.* 2008;26:1879–1885.