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市販後臨床試験の実際と問題点：FACS試験を省みて**

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Impact of FACS trial, a Large-scale Trial to Evaluate 3 New Anti-cancer Drugs for Advanced Non-small-cell Lung Cancer, on Japanese Postmarketing Reexamination System**

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Summary

The FACS trial was a 4-arm cooperative randomized phase III study of cisplatin plus irinotecan versus carboplatin plus paclitaxel, cisplatin plus gemcitabine, and cisplatin plus vinorelbine for advanced non-small lung cancer (NSCLC), carried out from October 2000 to June 2002 in Japan. This study was designed as a postmarketing study to reexamine 3 new anti-cancer drugs (paclitaxel, gemcitabine, and vinorelbine) following Japanese government approval of their use for NSCLC. According to the guidelines at the time for the development of anti-cancer drugs, such studies were required for the establishment of standard combined drug therapy. However, large-scale studies were very time-consuming. In contrast, the FACS study, which involved recruitment of 600 advanced cases with NSCLC, has been completed within 1 year and 10 months. Analysis of efficacy and toxicity showed superior or similar results to those of the ECOG study carried out during the same period. In other words, it was demonstrated that a large-scale comparative phase III study of lung cancer therapy could be done in Japan quickly and with high quality. Since then, several large-scale comparative trials have been done in lung cancer patients to evaluate the efficacy and toxicity of anti-cancer drugs. In this sense, the FACS trial was a milestone study for evaluation of new anti-cancer drugs in a large number of cancer patients. To fully establish the evaluation system for anti-cancer drugs, oncology study groups, such as the West Japan Oncology group (WJOG), which have rapidly completed several large-scale trials of lung cancer, should receive support from the government.

Key words

FACS trial, Cisplatin, Carboplatin, Irinotecan, Taxol, Gemcitabine, Vinorelbine, Non-small-cell lung cancer (NSCLC)